

EXHIBIT 224

From: "Parsons, Nancy Meyer" <nancy.parsons@hoganlovells.com> ["Parsons, Nancy Meyer" <nancy.parsons@hoganlovells.com>]
Sent: Friday, September 24, 2010 12:47:49 AM
To: "julie.kane@novartis.com" <julie.kane@novartis.com>;
 "cynthia.cetani@novartis.com" <cynthia.cetani@novartis.com>;
 "jeff.benjamin@novartis.com" <jeff.benjamin@novartis.com>;
 "steve.sokolow@novartis.com" <steve.sokolow@novartis.com>;
 "dorothy.watson@novartis.com" <dorothy.watson@novartis.com>;
 "sean.reilly@novartis.com" <sean.reilly@novartis.com>;
 "elizabeth.mcgee@novartis.com" <elizabeth.mcgee@novartis.com>;
 "ashley.pertsemlidis@novartis.com" <ashley.pertsemlidis@novartis.com>;
 "jill.dailey@novartis.com" <jill.dailey@novartis.com>;
 "jeff.rosenbaum@novartis.com" <jeff.rosenbaum@novartis.com>;
 "joseph.cacciatore@novartis.com" <joseph.cacciatore@novartis.com>;
 "ndillon@cravath.com" <ndillon@cravath.com>
CC: "Brady, Robert P." <robert.brady@hoganlovells.com>; "Evan Chesler" <EChesler@cravath.com>; "Smith, Michael F" <michael.f.smith@hoganlovells.com>
Subject: FW: Final portion of revised CIA
Attachments: NPC, Red-line of 9_15 draft CIA -- PART 2 (Sept 23, 2010).PDF

For your files.

From: Brady, Robert P.
 Sent: Thursday, September 23, 2010 8:46 PM
 To: 'Riordan, Mary E (OIG/OCIG)'; Melissa D. Hart Esq. (melissa.hart@oig.hhs.gov)
 Cc: 'Evan Chesler'
 Subject: Re: Final portion of revised CIA

Mary and Melissa-

As promised, here are our final revisions to the last portion of the draft CIA. Along with the other two sections sent to you earlier today, this constitutes the entire document. As I also discussed with Melissa, we will be providing our comments on the IRO appendices as quickly tomorrow as possible.

Thank you again for your time and consideration.

Hogan Lovells refers to the international legal practice comprising Hogan Lovells International LLP, Hogan Lovells US LLP, Hogan Lovells Worldwide Group (a Swiss Verein), and their affiliated businesses. Hogan Lovells International LLP is a limited liability partnership registered in England and Wales with registered number OC323639. Registered office and principal place of business: Atlantic House, Holborn Viaduct, London EC1A 2FG. Hogan Lovells US LLP is a limited liability partnership registered in the District of Columbia.

The word "partner" is used to refer to a member of Hogan Lovells International LLP or a partner of Hogan Lovells US LLP, or an employee or consultant with equivalent standing and qualifications, and to a partner, member, employee or consultant in any of their affiliated businesses who has equivalent standing. A list of the members of Hogan Lovells International LLP and of the non-members who are designated as partners, and of their respective professional qualifications, is open to inspection at the above address. Further important information about Hogan Lovells can be found on www.hoganlovells.com.

CONFIDENTIALITY. This email and any attachments are confidential, except where the email states it can be disclosed, it may also be privileged. If received in error, please do not disclose the contents to anyone, but notify the sender by return email and delete this email (and any attachments) from your system.

<<Missing Image>>

NPC DRAFT
SEPTEMBER 23, 2010

J. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives' interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. [QUESTION FOR OIG: Please confirm that this provision is intended to require the company to establish a FFMP program, not conduct the required audits, within 120 days of the Effective Date.] As described in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of sales representatives; and 3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

Prior to the Effective Date, Novartis had systems to address detailing, sampling, and medical inquiries. The detailing systems shall continue to include controls designed to ensure compliance with Federal health care program and FDA requirements and shall permit the tracking of detailing-related activities, including the submission of Inquiries (as defined above in Section III.B.2.g) and the distribution of samples of Government Reimbursed Products to HCPs. The detailing systems shall continue to include centralized mechanisms through which sales representatives may submit Inquiries to Medical Affairs. With regard to the distribution of samples, the detailing systems and its controls shall prevent the delivery of samples of particular Government Reimbursed Products to HCPs that Novartis has identified as belonging to a specialty group that is unlikely to prescribe the particular Government Reimbursed Product for a use consistent with the FDA-approved label for the product.

1. *Speaker Program Activities.* With regard to speaker programs, Novartis shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Novartis approved materials and may not directly or indirectly promote the product for off-label uses.) Novartis shall maintain ~~a centralized processes and related~~ electronic systems through which all speaker programs are tracked. This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs. Novartis shall ensure that speakers are paid and tracked according to a centrally managed process, and using a pre-set rate structure determined based on a fair-market value analysis conducted by Novartis. [NOTE TO OIG: As we discussed on 9/22, NPC currently relies on two electronic systems that apply the same set of business rules to manage the key elements of speaker program activities you identify above. This information feeds into centralized processes as relevant (e.g., PhRMA Code caps).]

NPC DRAFT
SEPTEMBER 23, 2010

Novartis shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, Novartis shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. Novartis shall require certified evaluations by sales representatives or other Novartis personnel regarding whether a speaker program complied with Novartis requirements, and in the event of non-compliance, Novartis shall ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, Novartis shall institute a Speaker Monitoring Program under which Novartis compliance personnel, other appropriately trained Novartis personnel who are independent from the functional area being monitored or outside personnel acting on behalf of Novartis shall attend speaker programs during each Reporting Period and conduct live audits of 50 the programs [XX number] of (Speaker Program Audits) and 50 documentation reviews of speaker programs. Speaker Program Audits conducted since July 1, 2010, shall be counted towards the First Reporting Period requirements. [NOTE TO OIG: Please refer to the data provided at our 7/29 meeting and in our subsequent 9/10 email to support these figures. Our proposal is well within the range required by other recent CIAs, particularly when considering that speaker program abuse was not central to our case. In addition, we continue to ask that auditing activities occurring since July 1, 2010, as part of the NPC 2010 audit plan, are counted towards the First Reporting Period requirements (we plan to conduct 25 speaker program audits during this time period). As we discussed on 9/22, giving some acknowledgment to companies that have voluntarily built strong self-audit programs encourages others in the industry to do the same. It also incentivizes companies entering into a CIA to continue these programs during negotiations (as NPC did in good faith), even in the face of imminent CIA monitoring obligations.]

[Note to Novartis: We are still evaluating the information provided by Novartis on this issue.] The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Novartis representative activities during the program to assess whether the programs were conducted in a manner consistent with Novartis' Policies and Procedures. Novartis shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Novartis U.S. compliance personnel, ~~or~~ other appropriately trained Novartis personnel who are independent from the monitored functional area, or appropriately trained and qualified outside personnel* acting on behalf of Novartis shall conduct observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and

NPC DRAFT
SEPTEMBER 23, 2010

with Novartis' Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by Novartis U.S. compliance personnel, ~~or~~ other appropriately trained Novartis personnel who are independent from the monitored functional area, or appropriately trained and qualified outside personnel* acting on behalf of Novartis, both on a risk-based targeting approach and on a sampling approach, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, Novartis U.S. compliance personnel, ~~or~~ other appropriately trained Novartis personnel who are independent from the monitored functional area, or appropriately trained and qualified outside personnel* acting on behalf of Novartis shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Novartis compliance personnel or other appropriately trained Novartis personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Novartis policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the sales representative.

Novartis U.S. compliance personnel, ~~or~~ other appropriately trained Novartis personnel who are independent from the monitored functional area, or appropriately trained and qualified outside personnel* acting on behalf of Novartis shall conduct at least ~~4~~ 50 Observations during each Reporting Period. ~~Observations conducted since July 1, 2010, shall be counted towards the First Reporting Period requirements.~~ Observations conducted since July 1, 2010, shall be counted towards the First Reporting Period requirements.

* Outside personnel acting on behalf of Novartis must be properly trained concerning FDA and Federal health care program requirements, the requirements of the CIA, and Novartis auditing policies and procedures.

[NOTE TO OIG: Please refer to the data provided at our 7/29 meeting and in our subsequent 9/10 email to support these figures. Our proposal is well within the range required by other recent CIAs, particularly when considered in the context of the 40,000+ ride-alongs that NPC sales management conducts annually (as discussed at our 7/29 meeting). In addition, as we discussed on 9/22, we continue to ask that OIG consider the use

29

Draft Novartis Corporate Integrity Agreement
September 15, 2010

SETTLEMENT COMMUNICATION
SUBJECT TO F.R.E. 408 AND 410
FOIA EXEMPT

NPC DRAFT
SEPTEMBER 23, 2010

of appropriately trained outside personnel (e.g., outside counsel) to conduct the required Observations. Based on our experience, we do not believe that there will be any change in the dynamic of the audit interaction if outside personnel are involved. All auditors are provided a protocol about how to conduct themselves and are generally referred to in interactions with HCPs as silent observers. This request will be particularly important if OIG increases the number of required Observations. A similar request was granted in the cases of Cephalon (p. 25) and Ortho (p. 23). We also continue to ask that auditing activities occurring since July 1, 2010, as part of the NPC 2010 audit plan, are counted towards the First Reporting Period requirements (see additional 9/15 email to this point). As we discussed on 9/22, giving some acknowledgment to companies that have voluntarily built strong self-audit programs encourages others in the industry to do the same. It also incentivizes companies entering into a CIA to continue these programs during negotiations (as did NPC in good faith), even in the face of imminent CIA monitoring obligations.]

3. *Records Reviews.* [Note to Novartis: We are still evaluating the information provided by Novartis on the issue of Records Reviews.] As a component of the FFMP, Novartis shall also review various types of records to assess sales representatives' interactions with HCPs and HClIs and to identify potential or actual compliance violations. For each Reporting Period, Novartis shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products and a sampling of the representatives promoting those products in every separate region. The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about Novartis' products provided by Novartis, upon request by the OIG no later than 90 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, Novartis shall select the three products to be reviewed.

~~These Records Reviews shall include the monitoring and review of: 1) records and systems relating to sales representatives' interactions with HCPs and HClIs relating to promotional speaker program activities, samples, meals, and other events or items (including records from the electronic detailing system for the particular sales representative, sales communications from managers, and expense reports); 2) requests for medical information; 3) tutorials and preceptorships; 4) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales representatives' interactions with HCPs and HClIs; 5) sales representative call notes; 6) sales representatives' e-mails; 2) — 7) recorded results of the Observations of sales representatives and applicable notes or information from the sales representatives' managers, 3) medical inquiry records that exceed a pre-determined threshold, 4) sample distribution records, 5) sales representative corporate charge card expense records, and 6) aggregate spend records concerning sales representative interactions with HCPs.~~

NPC DRAFT
SEPTEMBER 23, 2010

[NOTE TO OIG: We have revised this provision consistent with our 9/13 email summarizing the additional records we propose to review. Taken in whole, our Records Review proposal covers records that address sales representative spend on HCPs and other Customers, sampling, handling of medical inquiries, use of promotional messages and materials, adverse event reporting, and other compliance measures. Although we propose a different set of records than those you originally identified, we continue to take the position that our proposal reaches all the same types of conduct and achieves your intended objective. Preceptorships, though not addressed in our proposal, must all be reviewed and approved by the NPC Event Oversight Committee. NPC does not have call notes or generally have message recall studies about our products. Tailoring the list of specific records that must be reviewed to reflect the availability of individual companies' records and processes is not uncommon (see, e.g., Forest (no call notes), Ortho (no message recall or medical inquiry records), Allergan (no message recall or preceptorships), and Pfizer (no preceptorships or medical inquiries)).]

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the U.S. Ethics & Compliance Department for review and follow-up as appropriate. In the event that a potential violation of Novartis' Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, Novartis shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified in Speaker Program Activities, Observation and/or Records Review and any corrective action shall be recorded in the files of the U.S. Ethics & Compliance Department.

Novartis shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Novartis also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Novartis took as a result of such determinations. Novartis shall make the Observation reports for all other Observations available to the OIG upon request.

K. Monitoring of Non-Promotional Activities.

[Note to Novartis: Except for a few changes in Section III.K.4, we have not changed this section. We are still evaluating the information recently provided by Novartis.] To the

31

Draft Novartis Corporate Integrity Agreement
September 15, 2010

SETTLEMENT COMMUNICATION
SUBJECT TO F.R.E. 408 AND 410
FOIA EXEMPT

NPC DRAFT
SEPTEMBER 23, 2010

extent not already accomplished, within 120 days after the Effective Date Novartis shall develop and implement a monitoring program for the following types of activities: 1) consultant arrangement activities; 2) research-related activities; 3) publication activities; and 4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program. [NOTE TO OIG: Whether we can realistically meet the 120 day deadline turns on whether OIG will require monitoring of research and publications activities. We will need to revisit this once OIG has made its decision concerning Parts 2 and 3 of this Section below.]

1. *Consultant Arrangement Activities.* To the extent that Novartis engages U.S.-based HCPs or HCIs for services that relate to Promotional Functions or to Product Related Functions as defined in Sections II.C.4 and II.C.5 of this Agreement other than for speaker programs, research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. Novartis shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Novartis.

Novartis shall also prospectively review certain consultant arrangements, related to events, as described below. The review criteria may vary by type of arrangement, consistent with Novartis Event Oversight Committee and related policies, but, at minimum, shall include evaluation of the following for each proposed consultant arrangement: the business purpose/necessity of the engagement including the broader context of other approved events (i.e., a needs assessment), the general qualifications and experience of the consultant to provide the service, the number of consultants necessary, venue/location (as applicable), payment and anticipated expenses with (related to advisors), and compliance with other applicable legal standards. The members of the EOC include representatives from Ethics and Compliance (chair), Legal, Regulatory, Medical, and other disciplines as appropriate. When specifically identified in Novartis Event Oversight Committee policies as appropriate for more limited review, certain consulting arrangements will be reviewed by a representative of Ethics & Compliance or a smaller group including Ethics & Compliance. Approval by the designated reviewer(s) is required for the engagement to proceed. Violations of the policy (including failure to implement an event in compliance with the direction provided by the engagement reviewer(s)) will be referred for further investigation in accordance with company policy and may result in disciplinary action, up to and including termination.

The consultant arrangements subject to the prospective review are explicitly defined in current Novartis Event Oversight Committee policies. These include, but are not limited to, most types of consulting meetings, advisory boards, speaker training and novel types of promotional programs [NOTE TO OIG: All promotional materials are reviewed separately by a brand-specific Promotional Review Committee], and consultant programs for sales

NPC DRAFT
SEPTEMBER 23, 2010

representative training. [NOTE TO OIG: We have provided a brief description of our prospective EOC review process as proposed in our 8/27 purple-line and consistent with our discussions on 7/29 and 9/22.]

~~To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall establish a process to develop quarterly budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following quarter. The quarterly Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant related activities. Novartis' U.S. compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Novartis Policies and Procedures.~~

~~To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCLs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Novartis U.S. compliance personnel.~~

[NOTE TO OIG: As we discussed on 9/22, the objectives of the needs assessment and budget reviews are already accomplished by EOC review (please see our 9/13 submission on this point). EOC reviewers must evaluate whether there is a legitimate need for consulting arrangements/events. This assessment considers the individual event in the broader context of other similar events already approved. EOC reviewers also determine whether the budget for an individual arrangement is appropriate and reflects fair market value. Requiring a separate, parallel process for these assessments would be unnecessarily duplicative and would not advance our shared goal of improving the compliance posture of the company. See also preceding note in this section.]

To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Novartis received the work product generated by the Consultant.

Within 120 days after the Effective Date, Novartis shall establish a Consultant Monitoring

NPC DRAFT
SEPTEMBER 23, 2010

Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 20 ~~[XX number]~~ Consultant arrangements with HCPs. **[Note to Novartis: Please provide information about the types of consultant services for which Novartis engages HCPs and the annual numbers of each type of service. We will want this Consultant Monitoring Program to review various types of consultant services.]** [NOTE TO OIG: We provided this data verbally during our 7/29 meeting and in writing on 9/10.]

The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. ~~Novartis U.S. compliance personnel~~ Representatives conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Novartis' Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.

[NOTE TO OIG: As we discussed in concept at our 9/22 meeting and consistent with the advice of your office in your 9/17 email, we have agreed that retrospective auditing of the EOC process is required. That said, we hope you will consider the strength of our prospective review in determining the appropriate scope of this auditing. Further, as we discussed on 9/22, it is critical to the company to have the flexibility to use Novartis personnel other than Compliance and properly trained and qualified representatives outside of Novartis to conduct these reviews. Similar requests appear to have been granted in the case of Pfizer (p. 32-35) and Forest (p., 32-36).]

2. ~~Research-Related Activities.~~ To the extent that Novartis or any Novartis Affiliate (hereafter in this Section III.K.2, collectively "Novartis") engages U.S.-based HCPs or HCLs to conduct post-marketing research or to the extent that Novartis provides financial and other support to HCPs or HCLs for ISSs, such HCPs and HCLs shall be referred to collectively as "Researchers". Novartis shall require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid, and compliance obligations for the Researchers. Researchers shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair market value analysis conducted by Novartis.

To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall establish an annual budgeting plan for Researchers that identifies the business or scientific need for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. Novartis U.S.

NPC DRAFT
SEPTEMBER 23, 2010

~~compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with Novartis Policies and Procedures.~~

~~To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Novartis U.S. compliance personnel.~~

~~To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.~~

~~Within 120 days after the Effective Date, Novartis shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Program Audits) of at least [XX number] Researcher arrangements with HCPs or HCIs. [Note to Novartis: Please provide information about the numbers and types of Researchers that Novartis retains on an annual basis. We will want this Researcher Monitoring Program to review various types of Research arrangements.] The Researcher Monitoring Program shall review Researcher arrangements both on a risk-based targeting approach and on a sampling approach. Novartis U.S. compliance personnel conducting the Researcher Program Audits shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by Novartis and performed by the Researchers in a manner consistent with Novartis' Policies and Procedures. Results from the Researcher Program Audits, including identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.~~

[NOTE TO OIG: We continue to take the position that the NPC CIA should not include this provision. As we discussed during our 7/29 and 9/23 meetings, the company should receive some differentiation (see also 9/13 submission) . We are concerned that Pfizer (also Ortho, Lilly), as recidivist, does not have this obligation, but we do. As an aside, if this language remains in the document, we need to discuss, as generally identified on our 9/22 call, the specific obligations further (e.g., NPC does not have "clinical trial" budgets per se,

NPC DRAFT
SEPTEMBER 23, 2010

only product development budgets). Also, per M. Riordan's 9/21 call with R. Brady, we understand that the reference to "Novartis Affiliate" above was inadvertent.]

3. ~~Publication Activities.~~ To the extent that Novartis engages HCPs or HCLs to produce articles or other publications relating to Government Reimbursed Products (collectively, "Publication Activities") such HCPs or HCLs shall be referred to as Authors. Novartis shall require all Authors to enter written agreements describing the scope of work to be performed, the fees to be paid in connection with the Publication Activities, and compliance obligations of the Authors. Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair market value analysis conducted by Novartis.

~~To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publications Plans). The annual Publications Plan shall also identify the budgeted amounts to be spent on Publication Activities. Novartis' U.S. compliance personnel shall be involved in the review and approval of such annual Publications Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with Novartis Policies and Procedures.~~

~~To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall establish a needs assessment process for Publication Activities. This process shall ensure that a needs assessment has been completed prior to the retention of an Author for a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.) Any deviations from the Publications Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Novartis U.S. compliance personnel.~~

~~Within 120 days after the Effective Date, Novartis shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least [XX number] Publication Activities. [Note to Novartis: Please provide information about the numbers and types of Publication Activities in which Novartis engages on an annual basis. We will want this Publication Monitoring Program to review various types of Publication Activities.] The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach. Novartis U.S. compliance personnel conducting the Publication Monitoring Program shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with Novartis' Policies and~~

NPC DRAFT
SEPTEMBER 23, 2010

Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow up as appropriate.

[NOTE TO OIG: We continue to take the position that the NPC CIA should not include this provision. As we discussed during our 7/29 and 9/23 meetings, the company should receive some differentiation (see also 9/13 submission). We are concerned that several companies (e.g., Ortho, Lilly) who recently entered into CIAs with OIG do not have this obligation, but we do. As an aside, if this language remains in the document, we need to discuss, as generally identified on our 9/22 call, the specific obligations and timing further.]

4. *Medical Education Grant Activities.* Novartis represents that it has an established process housed within its Medical Department for the prospective review of medical education grants. All medical education grant requests received by Novartis are evaluated by individual(s) independent of Sales and Marketing. Novartis policy expressly prohibits the involvement of Sales and Marketing personnel in the medical education grant decision-making process.

Novartis represents that its sales and marketing departments have no involvement in, or influence over, the review and approval of medical education grants. Grant requests shall be submitted through an on-line process and requests are processed in accordance with standardized criteria developed by the grants office. Novartis shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date. **[NOTE TO OIG: NPC currently processes the majority of its grants through an online mechanism. However, a number continue to be processed manually. For several reasons, transitioning to an online-only system will require some changes to our current systems and processes.]**

To the extent not already accomplished, within 120 days after the Effective Date, Novartis shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least ~~XXX number~~ 30 medical education grants. **[Note to Novartis: Please provide information about the numbers and types of grants that Novartis provides on an annual basis. We may want this grants review to cover various types of grants.]** The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. Novartis U.S. compliance personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with

37

Draft Novartis Corporate Integrity Agreement
September 15, 2010

SETTLEMENT COMMUNICATION
SUBJECT TO F.R.E. 408 AND 410
FOIA EXEMPT

***NPC DRAFT
SEPTEMBER 23, 2010***

Novartis' Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate. [NOTE TO OIG: We recognize that we have proposed a relatively small number of audits more consistent with Allergan and Forest than Pfizer and AstraZeneca. We have based this on, what we believe to be, a relatively small number of medical education grants for a company of our size as well as a rigorous prospective review process initiated in 2006 and described to you in detail in our 9/13 submission.]

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of Novartis' Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, are identified during any aspect of the Non-Promotional Monitoring Program, Novartis shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the U.S. Compliance Department.

Novartis shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, Novartis also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Novartis' requirements or Policies and Procedures, and a description of the action(s) that Novartis took as a result of such determinations. Novartis shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

L. Notice to Health Care Providers and Entities. Within 90 days after the Effective Date, Novartis shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to all U.S.-based HCPs and HCEs that Novartis currently details. This notice shall be dated and shall be signed by Novartis' President. The body of the letter shall state the following:

As you may be aware, Novartis Pharmaceuticals Corporation (NPC) recently entered into a ~~global civil, criminal, and administrative~~ settlement with the United States and individual states in connection with the promotion and use of several of its products.

This letter provides you with additional information about the settlement, explains NPC's commitments going forward, and provides you with access to information

NPC DRAFT
SEPTEMBER 23, 2010

about those commitments. In general terms, the Government alleged that NPC unlawfully promoted the drugs Trileptal, Diovan, Zelnorm, Sandostatin, Exforge, and Tekturna. With respect to Trileptal, the Government alleged that NPC promoted the drug for uses not approved by the Food & Drug Administration (FDA). ~~—in violation of the Anti-Kickback Statute. The Government also alleged that NPC unlawfully promoted the drug Trileptal for uses not approved by the Food & Drug Administration (FDA).~~ To resolve these matters, Novartis pled guilty to a misdemeanor criminal violation of the Federal Food, Drug & Cosmetic Act (FDCA) in connection with Trileptal and agreed to pay a fine of \$185 million. With respect to Trileptal, Diovan, Zelnorm, Sandostatin, Exforge and Tekturna, the Government alleged that Novartis violated the False Claims Act. Novartis entered into a civil settlement to resolve those allegations, pursuant to which Novartis agreed to pay \$237.5 million to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: [Novartis shall include a link to the USAO, OCL, and Novartis websites in the letter.]

As part of the federal settlement, NPC also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, NPC agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by NPC's representatives to NPC's Ethics & Compliance Department or the Food & Drug Administration (FDA).

In addition, as part of our agreement with the government, we will disclose certain payments or transfers of value to U.S.-based Healthcare Professionals. This data will be posted in a prominent position on our website in an easily accessible and searchable list for public viewing.

Please call NPC at 1-800-xxx-xxx or visit us at [insert name of web link] if you have questions about the settlement referenced above or to report any instances in which you believe that a Novartis representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the FDA's Division of Drug Marketing, Advertising, and Communications at 301-796-1200. You should direct medical questions or concerns about the products to 1-800-526-7736.

NPC DRAFT
SEPTEMBER 23, 2010

The Chief Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notice shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Novartis shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments.

1. *Reporting of Payment Information.*

Phase I Reporting: On or before March 31, 2011, Novartis shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians who received Phase I Payments (as defined in Section III.M.2) directly or indirectly from Novartis during the fourth quarter of 2010 and the aggregate value of such Payments.

Thereafter, 60 days after the end of each calendar quarter, up to and including the third quarter of 2011, Novartis shall post on its website a report of the cumulative value of the Phase I Payments provided to each physician during the preceding calendar quarter. On or before March 1, 2012, Novartis shall also post on its website a report of the cumulative value of Phase I Payments provided to physicians by Novartis during 2011.

Phase II Reporting: On or before March 1, 2012, Novartis shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Phase II Payments (as defined in Section III.M.2) directly or indirectly from Novartis during the fourth quarter of 2011 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, Novartis shall post on its website a report of the cumulative value of the Phase II Payments provided to each physician during the preceding calendar quarter.

In addition, beginning on March 1, 2013, and 60 days after the end of each subsequent calendar year, Novartis shall post on its website a report of the cumulative value of the Phase II Payments and payments made pursuant to product research or development agreements and clinical investigations as described in §1128G(c)(E) of the Affordable Care Act (under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act)) provided to all U.S.-based physicians and Related Entities directly or indirectly from Novartis during the prior applicable calendar year. Payments to Related Entities will be included in reporting March 1, 2013, consistent with the Affordable Care Act. Each quarterly and annual report shall be easily accessible and readily searchable. The commencement of the Phase II Reporting will terminate the quarterly reporting obligations under Phase I Reporting. The

***NPC DRAFT
SEPTEMBER 23, 2010***

commencement of annual reports containing all payments required under the Affordable Care Act on March 1, 2013, will terminate the quarterly reporting requirements under Phase II Reporting.

Each listing made pursuant to this Section III.M shall include a complete list of all individual physicians or Related Entities ~~Entity~~ to whom or which Novartis made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entities ~~Entity~~ on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician has provided to Novartis for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount. Payments to Related Entities will be included in reporting March 1, 2013, consistent with the Affordable Care Act.

2. *Definitions and Miscellaneous Provisions.*

(i) Novartis shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. Novartis shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Novartis to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.M. 1, the term "Phase I Payments" is defined as payments, fees, honoraria, or compensation made by Novartis directly or indirectly in connection with promotional speaker programs and promotional speaker training to a physician in return for contracted services for Novartis to be performed expressly by the physician, with the exception of trips or travel, educational items, and meals (which are not otherwise covered or paid for by the Physician).

(iii) For purposes of Section III.M. 1, "Phase II Payments" is defined to include all "payments or transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder except as described below. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. ~~The term includes all payments~~

NPC DRAFT
SEPTEMBER 23, 2010

or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Novartis would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by Novartis or by a vendor retained by Novartis to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement. The term Payments does not include payments or other transfers of value made pursuant to product research or development agreements, or in connection with clinical investigations as described in §1128G(c)(1)(E) of the Affordable Care Act.

(iv) For purposes of its annual website posting above, and with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in §1128G(c)(E) of the Affordable Care Act, Novartis may delay the inclusion of such payments on its website listing consistent with §1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(v) The term "Payments" does not include transfers of value or other items that are not included in or are excluded from the definition of "payment" as set forth in §1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(vi) For purposes of this Section III.M, the term "Related Entity" is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

[NOTE TO OIG: As discussed briefly during our 9/22 meeting, the company is preparing for compliance with the Affordable Care Act but does not yet have capability to report payments made to "Related Entities." Specifically, our accounting systems do not currently allow for the tracking of payments to the individual HCP level when the check is paid to a corporation (e.g., medical partnership). The volume of payments via a vendor are generally more than those paid directly to HCPs by NPC. We are committed to resolving this, and are in the process of evaluating system and policy changes to address this issue. Notably, we have changed our processes so that payments made via a third party vendor are reported today in the name of the individual HCP (see an exception to this below). We expect to have the capability to report on payments made to "Related Entities" by the Affordable Care Act effective date in March 2013, but not by the Phase II timeline. These additional three months are critical to ensuring that our systems and processes are effectively capturing this data.]

We have a similar issue with respect to payments made to HCPs through contract research organizations (CROs). Currently NPC engages more than 20 CROs to manage their clinical investigations. The CROs, in turn, hire and pay individual investigators. This

NPC DRAFT
SEPTEMBER 23, 2010

represents the vast majority of payments made by Novartis to clinical investigators. Novartis does not currently have access to all of this payment data. As is the case with the Related Entity payments, we are committed to resolving this issue and are currently evaluating solutions on a priority basis. However, we will not be in a position to meet your deadline. We believe that we will be able to report these payments by March 1, 2013.

We would also like to ensure that we are afforded the protections provided by Congress in the Affordable Care Act for payment information concerning product development that could include confidential commercial information or trade secrets. Our proposed language above requesting a delayed reporting of these payments consistent with the Affordable Care Act is nearly identical the provision included in the recent Forest CIA (p. 40).

Finally, we added a sentence to clarify our interpretation of when Phase II quarterly reporting terminates.]

N. Other Transparency/Disclosure Initiatives.

Beginning on February 28, 2011, consistent with the phased-in process described in this section, Novartis represents that on an annual basis, it will post on its company website the following information with respect to both medical education grants and charitable contributions: 1) the ultimate recipient organization's name, to the extent known by Novartis; 2) a brief description of the program for which the grant or charitable contribution was requested; and 3) the amount of the grant or charitable contribution. Novartis shall continue to post (and provide updates to) the above-described information about medical education and charitable contribution grants throughout the term of this CIA. Novartis shall notify the OIG in Novartis' Consolidated Monthly Report of any material change in the substance of its policies regarding the funding of medical education grants and charitable contributions or posting of the above-referenced information relating to such funding.

Phase I Reporting: On or before February 28, 2012, Novartis shall post in a prominent position on its website a listing of information about medical education grants and charitable contributions provided to healthcare related organizations, defined as and limited to medical education grants and charitable contributions processed through Novartis' Grant Central Station during the calendar year 2011. Grants include continuing medical education ("CME") and non-CME funding requests; charitable contributions include funding to a healthcare related charitable organization in which the contribution's purpose is: (1) related to patient disease state education; (2) to provide health screening; or (3) to improve patient access to treatment.

Phase II Reporting: On or before August 30, 2012, February 28, 2013, Novartis shall post in a prominent position on its website a listing of information about Phase I Payments described

NPC DRAFT
SEPTEMBER 23, 2010

above, plus addition medical education grants and charitable contributions provided to health care related organizations processed through other payment mechanisms beyond GCS for the first two quarters of 2012. medical education grants and charitable contributions provided to healthcare related organizations during the calendar year 2012. These additional payments are defined as and limited to certain Philanthropic Grants, such as funding educational initiatives involving community initiatives and health awareness programs; Fundraising Contributions intended to provide support to the mission and activities of a non-profit, tax exempt organization; Dues provided to a non-profit group or organization for patient advocacy, professional societies or advisory panels to the organization; and Sponsorships provided to a non-profit, tax-exempt organizations to enable the organization to continue its mission and activities for an entire organization or for a specific event. Thereafter, 60 days after the end of each calendar year, Novartis shall post on its website a report of the value of Phase II Payments provided to each healthcare related organization, as defined above, during the preceding calendar year for the term of this agreement.

The commencement of Phase II reporting will terminate the annual reporting requirements under Phase I Reporting.

[NOTE TO OIG: The majority of Novartis' grants are processed through GCS, a system that was originally designed for medical education grants. In response to the call for increased transparency for all types of grants and charitable contributions, Novartis is currently evaluating the transfer of all grant requests received by the company to an online tool. However, today, a number of grants continue to be processed and reviewed internally outside the GCS system. Importantly, they do have internal review and controls, but process of payments has yet to be incorporated into the GCS tracking system. This is a policy and administrative issue that we hope to resolve shortly. As a compromise position, we have proposed above to omit these grants from Phase I reporting but to accelerate Phase II reporting and include them in this disclosure.]

Novartis represents that it will requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Novartis that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. Novartis shall continue this requirement throughout the term of this CIA. Within 120 days after the Effective Date, Novartis shall amend its policies relating to Consultants to explicitly state Novartis' requirement about full disclosure by Consultants consistent with the requirements of any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after ~~420~~ 150 days following the Effective Date, Novartis shall include an explicit requirement that the Consultants fully comply with applicable disclosure requirements and disclose their relationship with Novartis as required pursuant to their affiliation with any HCI,

NPC DRAFT
SEPTEMBER 23, 2010

medical committee, or other medical or scientific organization. [NOTE TO OIG: In a company the size of Novartis, we simply need additional time to implement the contract requirement.]

Novartis represents that it expects all Authors of biomedical manuscripts to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Novartis and to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 120 days after the Effective Date, Novartis shall amend its policies relating to Authors to explicitly state Novartis' requirement about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts with Authors and in any new contracts with Authors entered into after 120 days following the Effective Date, Novartis shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Novartis, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

Novartis [represents] [NOTE TO OIG: The company has been conducting due diligence to ensure its compliance with the anticipated CIA. In light of this, we are assessing our ability to make this assertion. We plan to follow-up with you promptly to discuss how to address this in the final document.] that it registers all clinical studies and a summary of results of such studies involving individuals on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov) consistent with all current federal requirements. Novartis shall continue to comply with Federal health care program requirements, or other applicable requirements relating to the reporting of clinical study information throughout the term of this CIA. In addition, if there is a change in Federal health care program requirements, FDA requirements, or other applicable requirements relating to the reporting of clinical study information, Novartis shall fully comply with such requirements.

Within 120 days of the Effective Date, Novartis shall posts information on its company website about postmarketing commitments (PMCs). The Novartis website shall provides access to general information about the PMC process, including study descriptions and information about the nature and status of FDA post-marketing commitments. Novartis shall continue to post the above-described information about PMCs on its website throughout the term of this CIA. [NOTE TO OIG: Novartis does not currently post information about PMCs on its website, nor has it, to our knowledge, represented otherwise. We need to tweak our company website, draft explanatory content, and develop a new process to report this information on our website in a patient-friendly format. We anticipate that we will need approximately 120 days to complete these tasks.]

45

Draft Novartis Corporate Integrity Agreement
September 15, 2010

SETTLEMENT COMMUNICATION
SUBJECT TO F.R.E. 408 AND 410
FOIA EXEMPT

NPC DRAFT
SEPTEMBER 23, 2010

Formatted:
Footnote,
Automatically adjust
right indent when
grid is defined

From: Evan Chesler [CN=Evan Chesler/OU=NY/O=Cravath]
Sent: Wednesday, March 17, 2010 8:18:28 PM
To: "Karen F. Green" <karen.green@wilmerhale.com>; "Ronald H Levine" <rlevine@postschell.com>; "Nina Dillon" <NDillon@cravath.com>
CC: "Jeffrey Benjamin" <jeff.benjamin@novartis.com>; "Steven P. Sokolow" <steve.sokolow@novartis.com>
Subject: Fw: Government Dollars on the 5 drugs
Attachments: Zelnorm_Chart_2002 to 2009.pdf; Diovan_Chart_2002 to 2009.pdf; Exforge_Chart_2007 to 2009.pdf; Sandostatin_Chart_2002 to 2009.pdf; Tekturna_Chart_2007 to 2009.pdf

----- Original Message -----

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 03/17/2010 03:31 PM AST
To: Evan Chesler
Subject: Government Dollars on the 5 drugs

Evan

As requested, attached are government dollars by program for each of the 5 drugs.

<<Zelnorm_Chart_2002 to 2009.pdf>> <<Diovan_Chart_2002 to 2009.pdf>>
<<Exforge_Chart_2007 to 2009.pdf>> <<Sandostatin_Chart_2002 to 2009.pdf>> <<Tekturna_Chart_2007 to 2009.pdf>>

Marilyn May
Deputy Chief, Affirmative Civil Litigation
U.S. Attorney's Office
Eastern District of Pennsylvania
(215)861-8308
marilyn.may@usdoj.gov

<<Missing Image>> [KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr]
[KO_Object_Attchmnt_Plchldr]

DIOVAN

	2002	2003	2004	2005	2006	2007	2008	2009	TOTAL 2002-2009
VA	\$3,858,930.71	\$4,968,261.07	\$9,161,639.87	\$8,943,713.19	\$9,748,216.95	\$10,672,442.22	\$11,308,445.37	\$4,514,308.44	\$63,175,957.82
DSCP Defense Supply Center	\$4,563,450.72	\$8,125,582.95	\$9,874,778.79	\$10,011,986.63	\$9,099,699.17	\$11,094,165.94	\$2,962,736.94	\$1,100,761.13	\$56,833,162.27
TRICARE	\$16,181,005.78	\$25,330,897.05	\$43,369,209.38	\$51,150,907.12	\$52,167,017.81	\$62,070,982.62	\$46,994,261.76	\$20,602,158.59	\$317,866,440.11
MEDICAID	\$95,503,598.95	\$150,028,004.14	\$195,158,718.15	\$238,360,764.40	\$78,247,852.00	\$79,373,087.00	\$89,352,417.00	not yet available	\$926,024,441.64
OPM	\$5,250,837.75	\$25,037,052.78	\$31,549,114.90	\$35,720,735.90	\$34,318,225.67	\$41,375,166.13	\$46,552,191.84	\$21,536,911.33	\$241,340,236.30
MEDICARE D	\$0.00	\$0.00	\$0.00	\$0.00	\$183,417,716.19	\$242,367,335.81	\$288,361,654.23	\$97,312,203.54	\$811,458,909.77
TOTALS	\$125,357,823.91	\$213,489,797.99	\$289,113,461.09	\$344,188,107.24	\$366,998,727.79	\$446,953,179.72	\$485,531,707.14	\$145,066,343.03	\$2,416,699,147.91

EXFORGE

	2007	2008	2009	TOTAL 2007-2009
VA	\$16,667.82	\$61,299.50	\$28,782.32	\$106,749.64
DSCP Defense Supply Center	\$2,575.65	\$27,149.93	\$36,566.78	\$66,292.36
TRICARE	\$794,674.55	\$4,268,533.21	\$2,408,684.55	\$7,471,892.31
MEDICAID	\$583,585.00	\$4,043,339.00	not yet available	\$4,626,924.00
OPM	\$639,924.24	\$3,768,700.65	\$2,127,988.62	\$6,536,613.51
MEDICARE D	\$1,960,769.41	\$11,224,202.78	\$5,009,941.64	\$18,194,913.83
TOTALS	\$3,998,196.67	\$23,393,225.07	\$9,611,963.91	\$37,003,385.65

SANDOSTATIN

	2002	2003	2004	2005	2006	2007	2008	2009	TOTAL 2002-2009
VA	\$4,633,744.49	\$6,397,419.49	\$8,072,205.59	\$8,685,151.69	\$9,368,252.21	\$8,835,592.92	\$9,440,010.23	\$4,043,426.78	\$59,475,803.40
DSCP Defense Supply Center	\$1,434,096.94	\$2,509,286.81	\$2,478,181.01	\$2,721,948.01	\$2,815,553.71	\$3,323,523.55	\$2,688,881.06	\$1,329,285.99	\$19,300,757.08
TRICARE	\$2,606,162.90	\$3,121,794.92	\$4,148,911.30	\$5,127,336.60	\$5,706,767.59	\$6,046,822.60	\$4,948,260.22	\$1,900,264.24	\$33,606,320.37
MEDICAID	\$15,701,052.61	\$23,313,706.84	\$20,158,854.96	\$25,009,759.75	\$11,979,468.45	\$9,717,983.63	not yet available	not yet available	\$105,880,826.24
OPM	\$1,264,964.81	\$1,287,162.17	\$1,331,773.52	\$1,481,147.24	\$1,137,287.91	\$1,000,347.55	\$987,807.47	\$412,484.76	\$8,902,975.43
MEDICARE D	\$0.00	\$0.00	\$0.00	\$0.00	\$9,619,575.34	\$10,501,801.06	\$10,990,696.33	\$3,985,458.99	\$35,097,531.72
MEDICARE B	\$50,825,783.00	\$34,042,383.00	\$50,216,369.00	\$154,776,569.00	\$85,814,895.00	\$93,429,677.00	\$102,581,151.00	\$77,352,629.00	\$649,039,456.00
TOTALS	\$76,465,804.75	\$70,671,753.23	\$86,406,295.38	\$197,801,912.29	\$126,441,800.21	\$132,855,748.31	\$131,636,806.31	\$89,023,549.76	\$911,303,670.24

TEKTURNA

	2007	2008	2009	TOTAL 2007-2009
VA	\$25,777.58	\$56,217.57	\$32,553.53	\$114,548.68
DSCP Defense Supply Center	\$17,452.77	\$117,742.90	\$119,297.63	\$254,493.30
TRICARE	\$677,996.80	\$2,375,847.11	\$1,389,730.68	\$4,443,574.59
MEDICAID	\$710,502.00	\$2,412,037.00	not yet available	\$3,122,539.00
OPM	\$445,380.15	\$1,476,125.79	\$802,590.57	\$2,724,096.51
MEDICARE D	\$2,565,592.95	\$9,955,753.92	\$4,385,330.93	\$16,906,677.80
TOTALS	\$4,442,702.25	\$16,393,724.29	\$6,729,503.34	\$27,565,929.88

ZELNORM

	2002	2003	2004	2005	2006	2007	2008	2009	TOTAL 2002-2009
VA	\$6,570.06	\$104,155.32	\$445,981.87	\$1,010,893.87	\$1,621,198.93	\$526,377.39			\$3,715,177.44
DSCP Defense Supply Center	\$5,779.73	\$300,907.21	\$891,378.20	\$1,603,291.17	\$3,093,576.20	\$2,165,051.02	\$515.19		\$8,060,498.72
TRICARE	\$262,589.99	\$3,670,527.92	\$8,952,308.27	\$14,030,522.21	\$20,868,210.85	\$6,207,380.23			\$53,991,539.47
MEDICAID	\$1,480,782.43	\$22,250,496.57	\$46,752,597.36	\$67,748,916.99	\$33,741,175.40	\$9,936,301.00	\$29,839.00		\$181,940,108.75
OPM	\$232,678.57	\$2,319,668.94	\$4,670,526.18	\$6,565,271.26	\$7,864,303.84	\$2,267,505.77	\$53,287.26	\$1,054.22	\$23,974,296.04
MEDICARE D	\$0.00	\$0.00	\$0.00	\$0.00	\$47,264,197.10	\$9,257,973.31	\$1,111.56		\$56,523,281.97
TOTALS	\$1,988,400.78	\$28,645,755.96	\$61,712,791.88	\$90,958,895.50	\$114,452,662.32	\$30,360,588.72	\$84,753.01	\$1,054.22	\$328,204,902.39

From: Evan Chesler [CN=Evan Chesler/OU=NY/O=Cravath]
Sent: Friday, February 12, 2010 7:56:19 PM
To: "Jeffrey Benjamin" <jeff.benjamin@novartis.com>; "Steven P. Sokolow" <steve.sokolow@novartis.com>; "Karen F. Green" <karen.green@wilmerhale.com>; "Ronald H Levine" <rlevine@postschell.com>
CC: "Stephen Madsen" <SMadsen@cravath.com>; "Nina Dillon" <NDillon@cravath.com>
Subject: Fw: new date

----- Original Message -----

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 02/12/2010 02:54 PM EST
To: Evan Chesler
Subject: RE: new date

yes

Marilyn May

Deputy Chief, Affirmative Civil Litigation

U.S. Attorney's Office

Eastern District of Pennsylvania

(215)861-8308

marilyn.may@usdoj.gov

From: EChesler@cravath.com [mailto:EChesler@cravath.com]
Sent: Friday, February 12, 2010 2:54 PM
To: May, Marilyn (USAPAE)
Subject: Re: new date

Marilyn.

Since that is a Mon, ok if we start @ 11 so we can travel that morning?

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 02/12/2010 02:00 PM EST
To: Evan Chesler
Subject: new date

Since one of the dates is next week, I wanted to get back to you as soon as possible-left you a message earlier today.

March 1 works best for us.

Thanks

Marilyn May

Deputy Chief, Affirmative Civil Litigation

U.S. Attorney's Office

Eastern District of Pennsylvania

(215)861-8308

marilyn.may@usdoj.gov

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: Evan Chesler [CN=Evan Chesler/OU=NY/O=Cravath]
Sent: Friday, March 12, 2010 1:24:48 PM
To: "Nina Dillon" <NDillon@cravath.com>
Subject: Fw: Projector

----- Original Message -----

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 03/12/2010 08:13 AM EST
To: Evan Chesler
Subject: RE: Projector

Already taken care of, but thanks for the reminder.

Marilyn May
Deputy Chief, Affirmative Civil Litigation
U.S. Attorney's Office
Eastern District of Pennsylvania
(215)861-8308
marilyn.may@usdoj.gov

-----Original Message-----

From: EChesler@cravath.com [mailto:EChesler@cravath.com]
Sent: Friday, March 12, 2010 7:59 AM
To: May, Marilyn (USAPAE)
Subject: Projector

May we use yours on Monday?

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: Evan Chesler [CN=Evan Chesler/OU=NY/O=Cravath]
Sent: Monday, February 22, 2010 6:35:07 PM
To: "Stephen Madsen" <SMadsen@cravath.com>; "Nina Dillon" <NDillon@cravath.com>
Subject: Fw: Two things

I have told Jeff we can start at noon.

----- Original Message -----

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 02/22/2010 12:25 PM EST
To: Evan Chesler
Subject: RE: Two things

ok

Marilyn May
Deputy Chief, Affirmative Civil Litigation
U.S. Attorney's Office
Eastern District of Pennsylvania
(215)861-8308
marilyn.may@usdoj.gov

-----Original Message-----

From: EChesler@cravath.com [mailto:EChesler@cravath.com]
Sent: Monday, February 22, 2010 11:58 AM
To: May, Marilyn (USAPAE)
Subject: Two things

1. I'll get the (new) draft to you tomw.
2. For the meeting on 3/15, can we start around noon and take whatever part of the afternoon we/you agree upon (ie, are there timing constraints, including any need to start earlier in the day)?

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: jeff.benjamin@novartis.com [jeff.benjamin@novartis.com]
Sent: Monday, May 10, 2010 9:25:05 PM
To: thomas.werlen@novartis.com; robert.pelzer@novartis.com;
martin.henrich@novartis.com; steve.sokolow@novartis.com;
paul_david.burns@novartis.com; dorothy.watson@novartis.com;
echesler@cravath.com; karen.green@wilmerhale.com; rlevine@postschell.com;
julie.kane@novartis.com
CC: sandra.mielke@novartis.com; carole.lewis@novartis.com;
linda.rubino@novartis.com; kathleen.fay@novartis.com;
karolina.simic@novartis.com; muriel.seiler@novartis.com; mcruz@cravath.com;
lucia.demayrinck@wilmerhale.com; diana.kehoe@novartis.com;
ndillon@cravath.com; rpbrady@hhlaw.com; cynthia.cetani@novartis.com
Subject: Privileged & Confidential - NPC Steering Committee Call: May 12th
Attachments: NPC, OIG Presentation Slide Deck (May 5, 2010) [Circulated to CIA Counsel
Team].PPT; NPC, OIG Leave Behind Slide Deck (May 5, 2010) [Circulated to CIA
Counsel Team].PPT; NPC INVESTIGATIONS CALENDAR 2010.doc;
Scan_Attachment.PDF

**Redacted:
Privilege**

Jeff Benjamin
Vice President
General Counsel Litigation

Novartis Corporation
608 Fifth Avenue
New York, NY 10020
Tel: 212 830 2466
Fax: 212 830-2404
Email: jeff.benjamin@novartis.com

<<Missing Image>> [KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr]

[Date]

PRIVILEGED AND CONFIDENTIAL

**Redacted:
Privilege**

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

Redacted:
Privilege

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**

**Redacted:
Privilege**



U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

*Frank R. Costello, Jr.
Direct Dial: (215) 861-8442
Facsimile: (215) 861-8618
E-mail Address: frank.costello@usdoj.gov*

*615 Chestnut Street
Suite 1250
Philadelphia, Pennsylvania 19106-4476
(215) 861-8200*

May 3, 2010

Karen F. Green, Esquire
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

Ronald H. Levine, Esquire
Post & Schell
Four Penn Center
1600 John F. Kennedy Boulevard
Philadelphia, PA 19103-2808

Evan R. Chesler, Esquire
Cravath, Swaine, & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019-7475

Re: Novartis Pharmaceuticals Corp.

Dear Counsel:

The government will not file a criminal Information concerning Novartis Pharmaceuticals Corporation's (NPC) promotion of Trileptal until the earlier of: (a) September 30, 2010; (b) the date a global resolution involving Trileptal, Zelnorm, Diovan, Sandostatin, Exforge and Tekturna is reached; or (c) when the government determines, in its sole discretion, that NPC's internal investigation concerning its promotion of Zelnorm, Diovan, Sandostatin, Exforge and Tekturna, or the resulting negotiation of a global resolution, is not being conducted in good faith. If a determination is made under (c), the government will give NPC two weeks (14 days) notice of its decision to file the Information, as long as that date does not extend beyond September 30, 2010.

This letter supersedes the government's previous letter of April 23, 2010.

Please let us know if you have any questions.

Very truly yours,

MICHAEL L. LEVY
United States Attorney


KAREN S. MARSTON
FRANK R. COSTELLO, JR.
Assistant United States Attorneys

From: Evan Chesler [CN=Evan Chesler/OU=NYC/O=Cravath]
Sent: Wednesday, September 01, 2010 10:40:05 PM
To: Nina Dillon
Subject: Re: draft agreement

I'm confident you'll come through. If you can survive Britney Spears as a role model, you can get by this.

From: Nina Dillon/NYC/Cravath
To: Evan Chesler/NYC/Cravath@Cravath
Date: 09/01/2010 06:31 PM
Subject: Re: draft agreement

Yes. Assuming I survive the dentist.

From: Evan Chesler
To: Nina Dillon
Cc:
Date: 09/01/2010 05:57 PM EDT
Subject: Fw: draft agreement

Redacted: Privilege

----- Forwarded by Evan Chesler/NYC/Cravath on 09/01/2010 05:57 PM -----

From: "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>
To: <EChesler@cravath.com>
Date: 09/01/2010 05:55 PM
Subject: draft agreement

<<2010_09_01_17_49_34.pdf>>

Evan

Attached is a revised draft agreement incorporating language we discussed earlier this week as well as language you sent us yesterday. For the sake of moving things along given the time constraints, we are sending this to you now, all revisions have not yet been approved by our clients.

Please let us know if there are any major issues.

[attachment "2010_09_01_17_49_34.pdf" deleted by Nina Dillon/NYC/Cravath]

From: "Green, Karen" <Karen.Green@wilmerhale.com> ["Green, Karen" <Karen.Green@wilmerhale.com>]
Sent: Friday, February 12, 2010 7:48:13 PM
To: <echesler@cravath.com>; <jeff.benjamin@novartis.com>
CC: <ndillon@cravath.com>; <rlevine@postschell.com>; <SMadsen@cravath.com>; <steve.sokolow@novartis.com>
Subject: Re: Fw: new date

I agree as well.

Karen F. Green
WilmerHale
60 State Street
Boston, MA 02109 USA
+1 617 526 6207 (t)
+1 617 526 5000 (f)
karen.green@wilmerhale.com

From: EChesler@cravath.com <EChesler@cravath.com>
To: jeff.benjamin@novartis.com
Cc: Green, Karen; ndillon@cravath.com; rlevine@postschell.com; ^Cravath-Madsen Steve; steve.sokolow@novartis.com
Sent: Fri Feb 12 14:36:28 2010
Subject: Re: Fw: new date

Agree

From: jeff.benjamin
Sent: 02/12/2010 02:32 PM EST
To: Evan Chesler
Cc: "Karen F. Green" <karen.green@wilmerhale.com>; Nina Dillon; "Ronald H Levine" <rlevine@postschell.com>; Stephen Madsen; "Steven P. Sokolow" <steve.sokolow@novartis.com>
Subject: Re: Fw: new date

Thanks. Since March 1 is a Monday, it would be preferable if we could schedule late morning or early afternoon, don't you think?

Jeff Benjamin
Vice President
General Counsel Litigation
Chair, Ethics & Compliance
Audit Committee
Novartis Corporation
608 Fifth Avenue
New York, NY 10020
Tel: 212 830 2466
Fax: 212 830-2404
Email: jeff.benjamin@novartis.com

EChesler@cravath.com

02/12/2010 02:16 PM To

"Jeffrey Benjamin" <jeff.benjamin@novartis.com>, "Steven P. Sokolow" <steve.sokolow@novartis.com>, "Karen F. Green" <karen.green@wilmerhale.com>, "Ronald H Levine" <rlevine@postschell.com>

cc

"Stephen Madsen" <SMadsen@cravath.com>, "Nina Dillon" <NDillon@cravath.com>

Subject

Fw: new date

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 02/12/2010 02:00 PM EST
To: Evan Chesler
Subject: new date

Since one of the dates is next week, I wanted to get back to you as soon as possible-left you a message earlier today.

March 1 works best for us.

Thanks

Marilyn May

Deputy Chief, Affirmative Civil Litigation

U.S. Attorney's Office

Eastern District of Pennsylvania

(215)861-8308

marilyn.may@usdoj.gov

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: Evan Chesler [CN=Evan Chesler/OU=NY/O=Cravath]
Sent: Friday, February 12, 2010 7:36:28 PM
To: "Jeffrey Benjamin" <jeff.benjamin@novartis.com>
CC: "Karen F. Green" <karen.green@wilmerhale.com>; Nina Dillon; "Ronald H Levine" <rlevine@postschell.com>; Stephen Madsen; "Steven P. Sokolow" <steve.sokolow@novartis.com>
Subject: Re: Fw: new date

Agree

----- Original Message -----

From: jeff.benjamin
Sent: 02/12/2010 02:32 PM EST
To: Evan Chesler
Cc: "Karen F. Green" <karen.green@wilmerhale.com>; Nina Dillon; "Ronald H Levine" <rlevine@postschell.com>; Stephen Madsen; "Steven P. Sokolow" <steve.sokolow@novartis.com>
Subject: Re: Fw: new date

Thanks. Since March 1 is a Monday, it would be preferable if we could schedule late morning or early afternoon, don't you think?

Jeff Benjamin
Vice President
General Counsel Litigation
Chair, Ethics & Compliance
Audit Committee
Novartis Corporation
608 Fifth Avenue
New York, NY 10020
Tel: 212 830 2466
Fax: 212 830-2404
Email: jeff.benjamin@novartis.com

EChesler@cravath.com
02/12/2010 02:16 PM

To
"Jeffrey Benjamin" <jeff.benjamin@novartis.com>, "Steven P. Sokolow" <steve.sokolow@novartis.com>, "Karen F. Green" <karen.green@wilmerhale.com>, "Ronald H Levine" <rlevine@postschell.com>
cc
"Stephen Madsen" <SMadsen@cravath.com>, "Nina Dillon" <NDillon@cravath.com>
Subject
Fw: new date

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 02/12/2010 02:00 PM EST
To: Evan Chesler
Subject: new date

Since one of the dates is next week, I wanted to get back to you as soon as possible-left you a message earlier today.
March 1 works best for us.

Thanks

Marilyn May
Deputy Chief, Affirmative Civil Litigation
U.S. Attorney's Office
Eastern District of Pennsylvania
(215)861-8308
marilyn.may@usdoj.gov

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: steve.sokolow@novartis.com [steve.sokolow@novartis.com]
Sent: Friday, February 12, 2010 7:35:30 PM
To: jeff.benjamin@novartis.com
CC: EChesler@cravath.com; "Karen F. Green" <karen.green@wilmerhale.com>; "Nina Dillon" <NDillon@cravath.com>; "Ronald H Levine" <rlevine@postschell.com>; "Stephen Madsen" <SMadsen@cravath.com>
Subject: Re: Fw: new date

right

Jeff Benjamin/GP/Novartis
02/12/2010 02:34 PM

To
Steve Sokolow/GP/Novartis@PH
cc
EChesler@cravath.com, "Karen F. Green" <karen.green@wilmerhale.com>, "Nina Dillon" <NDillon@cravath.com>, "Ronald H Levine" <rlevine@postschell.com>, "Stephen Madsen" <SMadsen@cravath.com>
Subject
Re: Fw: new date

You meant Monday, and that's why I was suggesting a later start time to avoid the need to travel on Sunday.

Jeff Benjamin
Vice President
General Counsel Litigation
Chair, Ethics & Compliance
Audit Committee
Novartis Corporation
608 Fifth Avenue
New York, NY 10020
Tel: 212 830 2466
Fax: 212 830-2404
Email: jeff.benjamin@novartis.com

Steve Sokolow/GP/Novartis
02/12/2010 02:20 PM

To
EChesler@cravath.com
cc
"Jeffrey Benjamin" <jeff.benjamin@novartis.com>, "Karen F. Green" <karen.green@wilmerhale.com>, "Nina Dillon" <NDillon@cravath.com>, "Ronald H Levine" <rlevine@postschell.com>, "Stephen Madsen" <SMadsen@cravath.com>
Subject

Re: Fw: new date

Given that March 1 is a Sunday, what travel plans would people like to make? Train Sunday night, dinner etc ?

EChester@cravath.com
02/12/2010 02:16 PM

To
"Jeffrey Benjamin" <jeff.benjamin@novartis.com>, "Steven P. Sokolow"
<steve.sokolow@novartis.com>, "Karen F. Green"
<karen.green@wilmerhale.com>, "Ronald H Levine" <rlevine@postschell.com>
cc
"Stephen Madsen" <SMadsen@cravath.com>, "Nina Dillon"
<NDillon@cravath.com>
Subject
Fw: new date

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 02/12/2010 02:00 PM EST
To: Evan Chesler
Subject: new date
Since one of the dates is next week, I wanted to get back to you as soon as possible-left you a message earlier today.
March 1 works best for us.
Thanks
Marilyn May
Deputy Chief, Affirmative Civil Litigation
U.S. Attorney's Office
Eastern District of Pennsylvania
(215)861-8308
marilyn.may@usdoj.gov
This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: Evan Chesler [CN=Evan Chesler/OU=NY/O=Cravath]
Sent: Friday, February 12, 2010 7:46:58 PM
To: "Steven P. Sokolow" <steve.sokolow@novartis.com>; "Jeffrey Benjamin" <jeff.benjamin@novartis.com>
CC: "Karen F. Green" <karen.green@wilmerhale.com>; Nina Dillon; "Ronald H Levine" <rlevine@postschell.com>; Stephen Madsen
Subject: Re: Fw: new date

Ok

----- Original Message -----

From: steve.sokolow
Sent: 02/12/2010 02:43 PM EST
To: jeff.benjamin@novartis.com
Cc: Evan Chesler; "Karen F. Green" <karen.green@wilmerhale.com>; Nina Dillon; "Ronald H Levine" <rlevine@postschell.com>; Stephen Madsen
Subject: Re: Fw: new date

I suggest Evan call and nail down a time that avoids a Sunday travel if possible.

Jeff Benjamin/GP/Novartis
02/12/2010 02:39 PM

To
Steve Sokolow/GP/Novartis@PH
cc
EChesler@cravath.com, "Karen F. Green" <karen.green@wilmerhale.com>, NDillon@cravath.com, "Ronald H Levine" <rlevine@postschell.com>, SMadsen@cravath.com
Subject
Re: Fw: new date

I leave it to the group, but I can't imagine if we started at 11 AM or 1 PM we wouldn't finish in time, assuming Marilyn wanted to be done by 5 PM. We could of course go later. Avoiding Sunday travel is a preference not a requirement.

Jeff Benjamin
Vice President
General Counsel Litigation
Chair, Ethics & Compliance
Audit Committee
Novartis Corporation
608 Fifth Avenue
New York, NY 10020
Tel: 212 830 2466

Fax: 212 830-2404
Email: jeff.benjamin@novartis.com

Steve Sokolow/GP/Novartis
02/12/2010 02:36 PM

To
EChesler@cravath.com
cc
"Jeffrey Benjamin" <jeff.benjamin@novartis.com>, "Karen F. Green"
<karen.green@wilmerhale.com>, NDillon@cravath.com, "Ronald H Levine"
<rlevine@postschell.com>, SMadsen@cravath.com
Subject
Re: Fw: new date

right its a Mon. I am worried that if we start too late Mon we won't
finish

EChesler@cravath.com
02/12/2010 02:35 PM

To
"Steven P. Sokolow" <steve.sokolow@novartis.com>
cc
"Jeffrey Benjamin" <jeff.benjamin@novartis.com>, "Karen F. Green"
<karen.green@wilmerhale.com>, NDillon@cravath.com, "Ronald H Levine"
<rlevine@postschell.com>, SMadsen@cravath.com
Subject
Re: Fw: new date

It is a mon. I need to do some calendar checking about su, feb 28.

From: steve.sokolow
Sent: 02/12/2010 02:20 PM EST
To: Evan Chesler
Cc: "Jeffrey Benjamin" <jeff.benjamin@novartis.com>; "Karen F. Green"
<karen.green@wilmerhale.com>; Nina Dillon; "Ronald H Levine"
<rlevine@postschell.com>; Stephen Madsen
Subject: Re: Fw: new date

Given that March 1 is a Sunday, what travel plans would people like to
make? Train Sunday night, dinner etc ?

EChester@cravath.com
02/12/2010 02:16 PM

To
"Jeffrey Benjamin" <jeff.benjamin@novartis.com>, "Steven P. Sokolow"
<steve.sokolow@novartis.com>, "Karen F. Green"
<karen.green@wilmerhale.com>, "Ronald H Levine" <rlevine@postschell.com>
cc
"Stephen Madsen" <SMadsen@cravath.com>, "Nina Dillon"
<NDillon@cravath.com>
Subject
Fw: new date

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 02/12/2010 02:00 PM EST
To: Evan Chesler
Subject: new date
Since one of the dates is next week, I wanted to get back to you as soon
as possible-left you a message earlier today.
March 1 works best for us.
Thanks
Marilyn May
Deputy Chief, Affirmative Civil Litigation
U.S. Attorney's Office
Eastern District of Pennsylvania
(215)861-8308
marilyn.may@usdoj.gov
This e-mail is confidential and may be privileged. Use or disclosure of it
by anyone other than a designated addressee is unauthorized. If you are
not an intended recipient, please delete this e-mail from the computer on
which you received it.
This e-mail is confidential and may be privileged. Use or disclosure of it
by anyone other than a designated addressee is unauthorized. If you are
not an intended recipient, please delete this e-mail from the computer on
which you received it.

From: Evan Chesler [CN=Evan Chesler/OU=NYC/O=Cravath]
Sent: Wednesday, September 29, 2010 2:36:13 PM
To: Nina Dillon
Subject: Re: Fw: NPC Agreements--Signature pages

**Redacted:
Privilege**

From: Nina Dillon/NYC/Cravath
To: Evan Chesler/NYC/Cravath
Date: 09/29/2010 10:24 AM
Subject: Fw: NPC Agreements--Signature pages

**Redacted:
Privilege**

----- Forwarded by Nina Dillon/NYC/Cravath on 09/29/2010 10:22 AM -----

Keesha Mitchell <keesha.mitchell@ohioattorneygeneral.gov>
09/29/2010 09:05 AM

To "NDillon@cravath.com" <NDillon@cravath.com>
cc
Subject RE: NPC Agreements--Signature pages

Good morning Nina,

I don't believe we need any signatures yet. I'm still hoping to have all of the state agreements back in time to send them all to you in one batch before NPC actually enters its plea. I know the Information will be filed tomorrow but it was my understanding that the plea wasn't scheduled for tomorrow.

Thanks,
Keesha

From: NDillon@cravath.com [NDillon@cravath.com]
Sent: Wednesday, September 29, 2010 8:27 AM
To: Keesha Mitchell
Subject: Re: NPC Agreements--Signature pages

Hi Keesha,

Just touching base about the logistics of signing the agreement. Given we sign with each state, and some states will presumably not have signed by tomorrow, what signatures do you require from us today or tomorrow. I will be in my office after 10 today if it's easier to discuss by phone.

Thanks,
Nina

From: Keesha Mitchell [keesha.mitchell@ohioattorneygeneral.gov]
Sent: 09/28/2010 01:02 PM AST

To: "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>; Nina Dillon
Cc: Evan Chesler
Subject: RE: NPC Agreements--Signature pages

Nina,

We are fine with you adding whatever signatory information you believe is needed to NPC's signature page.

Keesha R. Mitchell
Section Chief, Health Care Fraud Section
Ohio Attorney General Richard Cordray
Phone: (614) 466-0722
Fax: (866) 441-4718
Email: keesha.mitchell@ohioattorneygeneral.gov

150 East Gay Street, 17th Floor
Columbus, Ohio 43215
www.ohioattorneygeneral.gov

Please Note: In the near future, my email address will change to keesha.mitchell@ohioattorneygeneral.gov and my old email address will cease to operate. My new email address is now functional, so please update your records (and any email list-serv that you may have me on) with keesha.mitchell@ohioattorneygeneral.gov

From: May, Marilyn (USAPAE) [mailto:Marilyn.May@usdoj.gov]
Sent: Tuesday, September 28, 2010 12:53 PM
To: Nina Dillon; Keesha Mitchell
Cc: Evan Chesler
Subject: RE: NPC Agreements--Signature pages

We were waiting to hear from you about who is signing. It is ok with us if you fill that in.

From: Nina Dillon [mailto:NDillon@cravath.com]
Sent: Tuesday, September 28, 2010 11:37 AM
To: May, Marilyn (USAPAE); keesha.mitchell@ohioattorneygeneral.gov
Cc: Evan Chesler
Subject: NPC Agreements--Signature pages

Marilyn and Keesha,

The signature pages on the current drafts are blank with respect to the name and position of the NPC signatory. Will it be acceptable to you if we fill this information in ourselves? We will recreate the existing page but add the missing information as appropriate. I would appreciate it if you could advise me whether this approach is acceptable.

Thank you,

Nina Dillon

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: "Green, Karen" <Karen.Green@wilmerhale.com> ["Green, Karen" <Karen.Green@wilmerhale.com>]
Sent: Wednesday, March 17, 2010 8:28:40 PM
To: <echesler@cravath.com>; <rlevine@postschell.com>; <ndillon@cravath.com>
CC: <jeff.benjamin@novartis.com>; <steve.sokolow@novartis.com>
Subject: Re: Government Dollars on the 5 drugs

Thanks.

Karen F. Green
WilmerHale
60 State Street
Boston, MA 02109 USA
+1 617 526 6207 (t)
+1 617 526 5000 (f)
karen.green@wilmerhale.com

From: EChesler@cravath.com <EChesler@cravath.com>
To: Green, Karen; rlevine@postschell.com; ndillon@cravath.com
Cc: jeff.benjamin@novartis.com; steve.sokolow@novartis.com
Sent: Wed Mar 17 16:18:28 2010
Subject: Fw: Government Dollars on the 5 drugs

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 03/17/2010 03:31 PM AST
To: Evan Chesler
Subject: Government Dollars on the 5 drugs

Evan

As requested, attached are government dollars by program for each of the 5 drugs.

<<Zelnorm_Chart_2002 to 2009.pdf>> <<Diovan_Chart_2002 to 2009.pdf>> <<Exforge_Chart_2007 to 2009.pdf>>
<<Sandostatin_Chart_2002 to 2009.pdf>> <<Tekturna_Chart_2007 to 2009.pdf>>

Marilyn May

Deputy Chief, Affirmative Civil Litigation

U.S. Attorney's Office

Eastern District of Pennsylvania

(215)861-8308

marilyn.may@usdoj.gov

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: "Green, Karen" <Karen.Green@wilmerhale.com> ["Green, Karen" <Karen.Green@wilmerhale.com>]
Sent: Tuesday, September 07, 2010 7:58:36 PM
To: "Nina Dillon" <NDillon@cravath.com>
Subject: RE: Novartis Relator Complaints 2

Nina:

**Redacted:
Privilege**

Thanks.

From: Nina Dillon [mailto:NDillon@cravath.com]
Sent: Tuesday, September 07, 2010 3:32 PM
To: Green, Karen
Subject: Fw: Novartis Relator Complaints 2

Karen,

**Redacted:
Privilege**

Nina

----- Forwarded by Nina Dillon/NYC/Cravath on 09/07/2010 03:31 PM -----

Nina Dillon/NYC/Cravath

09/07/2010 03:07 PM

To

jeff benjamin, steve sokolow, David Greenwald/NYC/Cravath, Ronald Levine

cc

Subject

Fw: Novartis Relator Complaints 2

----- Forwarded by Nina Dillon/NYC/Cravath on 09/07/2010 03:07 PM -----

Evan Chesler/NYC/Cravath

09/07/2010 02:58 PM

To

Nina Dillon/NYC/Cravath

cc

Subject

Fw: Novartis Relator Complaints 2

From: "Romero, Jacqueline (USAPAE)" [Jacqueline.Romero@usdoj.gov]
Sent: 09/07/2010 11:38 AM AST
To: Evan Chesler
Cc: "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>
Subject: Novartis Relator Complaints 2

Evan,

As explained in my previous email, attached please find the complaint filed by Relator Garrity against Novartis in the Eastern District of Pennsylvania.

Jacqueline

215-861-8470

<<Garrity.pdf>>

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: "Champa, Jessica (CIV)" <Jessica.Champa@usdoj.gov> ["Champa, Jessica (CIV)" <Jessica.Champa@usdoj.gov>]
Sent: Tuesday, September 28, 2010 9:48:40 PM
To: <NDillon@cravath.com>
CC: <echesler@cravath.com>; "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>
Subject: Re: Novartis Settlement Agreement

Thanks.

Jessica Sims Champa
Trial Attorney, Civil Frauds
202 353-2680

From: Nina Dillon [mailto:NDillon@cravath.com]
Sent: Tuesday, September 28, 2010 05:28 PM
To: Champa, Jessica (CIV)
Cc: Evan Chesler <EChesler@cravath.com>
Subject: Re: Novartis Settlement Agreement

Jessica,

Please see attached--truly minor.

Nina Dillon

"Champa, Jessica (CIV)" <Jessica.Champa@usdoj.gov>

09/28/2010 04:48 PM To
<NDillon@cravath.com>
cc
<echesler@cravath.com>, "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>
Subject
Novartis Settlement Agreement

Nina â€œ I understand that you have some minor, non-substantive edits on the settlement agreement. Please send them

to me as I am currently the custodian of the agreement and I will make the appropriate changes. Also, do you have an estimate of when you will be sending them? I need them ASAP. Thanks very much. - Jessica

Jessica Sims Champa
Trial Attorney
Civil Frauds
U.S. Department of Justice
601 D Street NW, Room 9016
Washington, D.C. 20004
direct: (202) 353-2680
fax: (202) 616-4286

USPS Mail to:
U.S. Department of Justice
Civil Division
Commercial Litigation Branch
P.O. Box 261
Ben Franklin Station
Washington, DC 20044

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov> ["May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>]
Sent: Tuesday, September 28, 2010 4:53:07 PM
To: "Nina Dillon" <NDillon@cravath.com>; <keesha.mitchell@ohioattorneygeneral.gov>
CC: "Evan Chesler" <EChesler@cravath.com>
Subject: RE: NPC Agreements--Signature pages

We were waiting to hear from you about who is signing. It is ok with us if you fill that in.

From: Nina Dillon [mailto:NDillon@cravath.com]
Sent: Tuesday, September 28, 2010 11:37 AM
To: May, Marilyn (USAPAE); keesha.mitchell@ohioattorneygeneral.gov
Cc: Evan Chesler
Subject: NPC Agreements--Signature pages

Marilyn and Keesha,

The signature pages on the current drafts are blank with respect to the name and position of the NPC signatory. Will it be acceptable to you if we fill this information in ourselves? We will recreate the existing page but add the missing information as appropriate. I would appreciate it if you could advise me whether this approach is acceptable.

Thank you,

Nina Dillon

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: steve.sokolow@novartis.com [steve.sokolow@novartis.com]
Sent: Friday, October 08, 2010 9:49:24 PM
To: "NDillon" <NDillon@cravath.com>; ken.schuster@novartis.com;
carl.briscoe@novartis.com; jeff.benjamin@novartis.com
Subject: Re: NPC Settlement

Ken :

Redacted: Privilege

Sent from my BlackBerry Wireless Handheld.

----- Original Message -----

From: NDillon
Sent: 10/08/2010 04:44 PM AST
To: Ken Schuster; Carl Briscoe; Steve Sokolow; Jeff Benjamin
Subject: Fw: NPC Settlement

This just in.

Nina

----- Original Message -----

From: Nina Dillon
Sent: 10/08/2010 04:33 PM EDT
To: "Harwell, Randy (USAFLM)" <Randy.Harwell@usdoj.gov>
Subject: Re: NPC Settlement

Thanks.

Nina

----- Original Message -----

From: "Harwell, Randy (USAFLM)" [Randy.Harwell@usdoj.gov]
Sent: 10/08/2010 03:45 PM AST
To: Nina Dillon
Cc: "Champa, Jessica (CIV)" <Jessica.Champa@usdoj.gov>; Evan Chesler
Subject: RE: NPC Settlement

Nina, attached are the wire instructions for the Novartis transfer. Note that the amount includes accrued interest as set forth in the settlement agreement.

Please let us know if the transfer will take place on a date other than October 14, so that we can plan accordingly. Thank you.

Randy Harwell

Assistant U.S. Attorney

tel. 813-274-6350

fax 813 274-6198

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: ken.schuster@novartis.com [ken.schuster@novartis.com]
Sent: Friday, October 08, 2010 9:51:29 PM
To: steve.sokolow@novartis.com; "NDillon" <NDillon@cravath.com>;
carl.briscoe@novartis.com; jeff.benjamin@novartis.com
Subject: Re: NPC Settlement

Redacted:
Privilege

----- Original Message -----

From: Steve Sokolow
Sent: 10/08/2010 05:49 PM EDT
To: "NDillon" <NDillon@cravath.com>; Ken Schuster; Carl Briscoe; Jeff Benjamin
Subject: Re: NPC Settlement

Ken : Redacted:
Privilege

Sent from my BlackBerry Wireless Handheld.

----- Original Message -----

From: NDillon
Sent: 10/08/2010 04:44 PM AST
To: Ken Schuster; Carl Briscoe; Steve Sokolow; Jeff Benjamin
Subject: Fw: NPC Settlement

This just in.

Nina

----- Original Message -----

From: Nina Dillon
Sent: 10/08/2010 04:33 PM EDT
To: "Harwell, Randy (USAFLM)" <Randy.Harwell@usdoj.gov>
Subject: Re: NPC Settlement

Thanks.

Nina

----- Original Message -----

From: "Harwell, Randy (USAFLM)" [Randy.Harwell@usdoj.gov]
Sent: 10/08/2010 03:45 PM AST
To: Nina Dillon
Cc: "Champa, Jessica (CIV)" <Jessica.Champa@usdoj.gov>; Evan Chesler
Subject: RE: NPC Settlement

Nina, attached are the wire instructions for the Novartis transfer. Note that the amount includes accrued interest as set forth in the settlement agreement.

Please let us know if the transfer will take place on a date other than October 14, so that we can plan accordingly. Thank you.

Randy Harwell

Assistant U.S. Attorney

tel. 813-274-6350

fax 813 274-6198

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: ken.schuster@novartis.com [ken.schuster@novartis.com]
Sent: Thursday, October 07, 2010 2:20:49 PM
To: Nina Dillon <NDillon@cravath.com>
CC: "jeff benjamin" <jeff.benjamin@novartis.com>; "steve sokolow" <steve.sokolow@novartis.com>; carl.briscoe@novartis.com
Subject: Re: Trileptal Fw: NPC Settlement

Nina

Redacted: Privilege

Carl Briscoe
Assistant Treasurer
Novartis Finance Corporation
608 Fifth Avenue
New York, NY 10020
Phone: 212 830 2464
Fax: 212 830 2487
Cell: 201 650 0120
Email : carl.briscoe@novartis.com

Ken

Ken Schuster
Vice President & Treasurer
Novartis Corporation
608 Fifth Avenue 10th Floor
New York, NY 10020
USA
Phone: +1 212 830 2434
Fax: +1 212 830 2492
Cell: +1 862 222 5928
Email : ken.schuster@novartis.com

Nina Dillon <NDillon@cravath.com>
10/05/2010 03:22 PM

To
ken.schuster@novartis.com
cc
"jeff benjamin" <jeff.benjamin@novartis.com>, "steve sokolow" <steve.sokolow@novartis.com>
Subject
Trileptal Fw: NPC Settlement

Ken,

Redacted: Privilege

Nina

----- Forwarded by Nina Dillon/NYC/Cravath on 10/05/2010 03:21 PM -----
"Harwell, Randy (USAFLM)" <Randy.Harwell@usdoj.gov>
10/05/2010 03:20 PM

To

"Nina Dillon" <NDillon@cravath.com>

cc

"Evan Chesler" <EChesler@cravath.com>, "Champa, Jessica (CIV)"
<Jessica.Champa@usdoj.gov>

Subject

RE: NPC Settlement

Nina, you are correct and we concur. We will expect the wire by COB
10/14/10. Thank you.

Randy Harwell
Assistant U.S. Attorney
tel. 813-274-6350
fax 813 274-6198

From: Nina Dillon [mailto:NDillon@cravath.com]
Sent: Tuesday, October 05, 2010 3:11 PM
To: Harwell, Randy (USAFLM)
Cc: Evan Chesler; Champa, Jessica (CIV)
Subject: RE: NPC Settlement

Thank you, Randy. I think the date should be the 14th, though, since
banks are closed Columbus day. Can you please confirm I calculated this
correctly?

Thanks,

"Harwell, Randy (USAFLM)" <Randy.Harwell@usdoj.gov>
10/05/2010 02:53 PM

To

"Nina Dillon" <NDillon@cravath.com>

cc

"Evan Chesler" <EChesler@cravath.com>, "Champa, Jessica (CIV)"
<Jessica.Champa@usdoj.gov>

Subject

RE: NPC Settlement

Nina, I've consulted with my colleague Jessica Champa regarding the payment date issue. We understand that Novartis' counsel was provided with the fully executed agreement on October 4. As the agreement permits payment of the settlement amount within seven business days of receipt of the executed agreement, we will expect payment by COB on October 13.

We will calculate the interest component as of October 13 and forward the wiring instructions to you, hopefully by tomorrow. If Novartis intends to pay in advance of October 13, please let me know. Thank you.

Randy Harwell
Assistant U.S. Attorney
tel. 813-274-6350
fax 813 274-6198

From: Harwell, Randy (USAFLM)
Sent: Monday, October 04, 2010 4:02 PM
To: 'Nina Dillon'
Cc: Evan Chesler; Champa, Jessica (CIV)
Subject: RE: NPC Settlement

Nina, Jessica Champa was out of the office today and so I was unable to discuss with her the issue of the date of payment for the Novartis settlement. We will try to reach you tomorrow morning about this. Thanks for your patience.

Randy Harwell
Assistant U.S. Attorney
tel. 813-274-6350
fax 813 274-6198

From: Nina Dillon [mailto:NDillon@cravath.com]
Sent: Wednesday, September 29, 2010 4:11 PM
To: Harwell, Randy (USAFLM)
Cc: Evan Chesler
Subject: NPC Settlement

Randy,

Evan Chesler forwarded your message from earlier today. Right now, NPC plans to make payment on the 7th business day following receipt by NPC's attorneys of the fully executed agreement. The relevant address is:

Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

The Tax ID is: 22-1857084

Please let me know if you have any further questions. We will be awaiting further instructions from you.

Regards,

Nina Dillon

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: Evan Chesler [CN=Evan Chesler/OU=NYC/O=Cravath]
Sent: Tuesday, August 24, 2010 12:08:59 AM
To: Nina Dillon
Subject: Fw: call

Call next Mon, probably @ 3. We can do it from my office.

----- Original Message -----

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 08/23/2010 08:05 PM AST
To: Evan Chesler
Subject: Re: call

That works for me. I would prefer the earlier side of that window if possible.

From: Evan Chesler [mailto:EChesler@cravath.com]
Sent: Monday, August 23, 2010 05:17 PM
To: May, Marilyn (USAPAE)
Subject: RE: call

How about any time between 3 and 5?

From: "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>
To: <EChesler@cravath.com>
Date: 08/23/2010 04:15 PM
Subject: RE: call

yes

From: EChesler@cravath.com [mailto:EChesler@cravath.com
<mailto:EChesler@cravath.com>]
Sent: Monday, August 23, 2010 4:10 PM
To: May, Marilyn (USAPAE)
Subject: Re: call

If you'll be in Monday, I'll send you all times that day that I can do.
Need to get to my calendar later today. Will Mon work?

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 08/23/2010 04:07 PM AST

To: Evan Chesler
Subject: RE: call

Sorry doesn't work. How about early next week

From: EChesler@cravath.com [mailto:EChesler@cravath.com
<mailto:EChesler@cravath.com>]
Sent: Monday, August 23, 2010 4:06 PM
To: May, Marilyn (USAPAE)
Subject: Re: call

It looks like my meeting will be over at about 3. Can we a call around 4?

From: "May, Marilyn (USAPAE)" [Marilyn.May@usdoj.gov]
Sent: 08/23/2010 02:21 PM AST
To: Evan Chesler
Subject: call

Evan

I have left you alone so you could focus on the state agreement, but I thought perhaps we could talk on Wednesday sometime about the settlement agreement.

Do you have any time on Wednesday? If not, it will have to be next week.

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: Evan Chesler [CN=Evan Chesler/OU=NYC/O=Cravath]
Sent: Tuesday, September 07, 2010 6:58:46 PM
To: Nina Dillon
Subject: Fw: Novartis Relator Complaints 1
Attachments: McKee.pdf; 08.20.10 Ex. A.pdf; 08.20.10 Ex. B.pdf; 08.20.10 Ex. C.pdf; 08.20.10 Ex. D.pdf; 08.20.10 Ex. E.pdf; 08.20.10 Ex. F.pdf; 08.20.10 Ex. G.pdf; 08.20.10 Ex. H.pdf

----- Original Message -----

From: "Romero, Jacqueline (USAPAE)" [Jacqueline.Romero@usdoj.gov]
Sent: 09/07/2010 11:38 AM AST
To: Evan Chesler
Cc: "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>
Subject: Novartis Relator Complaints 1

Evan,

Marilyn asked me to send you copies of the three complaints filed against Novartis in the Eastern District of Pennsylvania. Because of the volume of some of these files, I will be sending them in separate emails. Attached is the Complaint filed by Relator McKee with exhibits. Please call me with any questions.

Jacqueline
215-861-8470

<<McKee.pdf>> <<08.20.10 Ex. A.pdf>> <<08.20.10 Ex. B.pdf>>
<<08.20.10 Ex. C.pdf>> <<08.20.10 Ex. D.pdf>> <<08.20.10 Ex. E.pdf>>
<<08.20.10 Ex. F.pdf>> <<08.20.10 Ex. G.pdf>> <<08.20.10 Ex. H.pdf>>

<<Missing Image>> [KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr]
[KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr] [KO_Object_Attchmnt_Plchldr]
[KO_Object_Attchmnt_Plchldr]

0128327	EDWARD	HILL	3333 BROOKVIEW HILLS BLVD	WINSTON SALEM	NC	27103	N	1	1	1
1953842	CHRISTOPH	HUNT	2933 MAPLEWOOD AVE	WINSTON SALEM	NC	27103	N	3	3	3
1590567	DONG	HYUN	3333 BROOKVIEW HILLS BLVD	WINSTON SALEM	NC	27103	N	2	2	3
1341374	MARK	IPPOLITO	319 PENNY LN	CONCORD	NC	28025	N	3	2	3
0204598	TRAVIS	JACKSON	175 KIMEL PARK DR	WINSTON SALEM	NC	27103	N	1	2	3
0785160	DOUGLAS	JEFFERY	BOWMAN-GRAY SCH OF MED	WINSTON SALEM	NC	27157	N	3	3	3
0795132	BEVERLY	JONES	3880 VEST MILL RD	WINSTON SALEM	NC	27103	P	1	3	3
1732088	RAYMOND	KANDT	608 N ELM ST	HIGH POINT	NC	27282	N	3	2	3
0837498	RUPINDER	KAUR	829 GREEN VALLEY RD	GREENSBORO	NC	27408	P	1	3	3
0438859	DAVID	KELLY	300 S HAWTHORNE RD	WINSTON SALEM	NC	27103	N	3	3	3
1217946	LUCIE	LAUVE	2933 MAPLEWOOD AVE	WINSTON SALEM	NC	27103	N	3	2	1
0128512	JAMES	LOVE	1910 N CHURCH ST	GREENSBORO	NC	27405	N	1	2	1
0796962	MARK	LYERLY	138 POLO DR	SALISBURY	NC	28144	N	3	3	3
0388100	EUGENE	MADONIA	3 DUDLEY ST	MARTINSVILLE	VA	24112	N	3	2	2
0798347	JOHN	MALONE	423 S SOUTH ST	MOUNT AIRY	NC	27030	N	1	1	2
0438081	PAUL	MARTIN	3314 HEALY DR	WINSTON SALEM	NC	27103	N	1	3	3
0071763	THOMAS	MASCENIK	175 KIMEL PARK DR	WINSTON SALEM	NC	27103	N	2	3	2
0743028	SUZANNE	MCADAMS	895 STATE FARM RD	BOONE	NC	28807	N	1	2	2
0204604	ROGER	MCCAULEY	175 KIMEL PARK DR	WINSTON SALEM	NC	27103	P	3	2	3
1588483	MICHAEL	MCCLURE	320 BOULEVARD ST	HIGH POINT	NC	27282	P	3	2	3
0128302	JOE	MCWHORTER	2810 MAPLEWOOD AVE	WINSTON SALEM	NC	27103	N	3	3	3
0080862	DAVID	MEYER	175 KIMEL PARK DR	WINSTON SALEM	NC	27103	N	1	1	2
0764107	GREGORY	MIEDEN	608 N ELM ST	HIGH POINT	NC	27282	N	1	2	2
0429298	JOSEPH	MILLER	608 N ELM ST	HIGH POINT	NC	27282	N	1	2	3
0415508	ROBERT	MITCHELL	319 PENNY LN	CONCORD	NC	28025	N	3	2	2
1582287	ERIC	MOSER	624 QUAKER LN	HIGH POINT	NC	27282	N	2	2	2
0204678	VICTORIA	NEAVE	608 N ELM ST	HIGH POINT	NC	27282	N	3	3	3
0827832	JACALYN	NELSON	169 EXECUTIVE DR	DANVILLE	VA	24541	N	2	2	2
0797409	SUZANNE	NUTT	624 QUAKER LN	HIGH POINT	NC	27282	N	3	1	3
0843415	CORMAC	ODONOVAN	300 MEDICAL CENTER BLVD	WINSTON SALEM	NC	27157	N	3	1	3
1270710	VICTOR	OWUSU-YAW	129 BROAD ST	DANVILLE	VA	24541	N	1	1	2
0781515	FRANCOIS	PICOT	319 PENNY LN	CONCORD	NC	28025	N	3	3	3
0089795	JOHN	PORTER	3333 BROOKVIEW HILLS BLVD	WINSTON SALEM	NC	27103	N	1	1	1
0482128	RENUKA	PRASAD	212 S MAIN ST	DANVILLE	VA	24541	P	1	1	3
0838687	KESHAVPAL	REDDY	522 N ELAM AVE	GREENSBORO	NC	27403	P	2	1	3
1915803	MICHAEL	REYNOLDS	1910 N CHURCH ST	GREENSBORO	NC	27405	N	3	2	3
1226453	PATRICK	REYNOLDS	W F U BAPTIST MEDICAL CTR MEDI	WINSTON SALEM	NC	27157	N	3	3	3
0439229	CAROL	RICHARDSON	522 N ELAM AVE	GREENSBORO	NC	27403	P	3	2	3
0128330	EWELL	ROACH	300 MEDICAL CENTER BLVD	WINSTON SALEM	NC	27157	N	3	2	3
2140646	JASON	ROSENBERG	300 MEDICAL CENTER BLVD	WINSTON SALEM	NC	27157	N	3	3	3
0811749	MARIA	SAM	300 S HAWTHORNE RD	WINSTON SALEM	NC	27157	N	3	2	3
0852998	CESAR	SANTOS	300 MEDICAL CENTER BLVD	WINSTON SALEM	NC	27157	N	3	2	3
1223808	RICHARD	SATER	624 QUAKER LN	HIGH POINT	NC	27282	N	1	2	3
0747195	DAVID	SCHMIDT	923 N 2ND ST	ALBEMARLE	NC	28001	N	1	2	2
0477760	JEFFREY	SCHMIDT	1910 N CHURCH ST	GREENSBORO	NC	27405	N	3	2	1
0790837	LORI	SCHNEIDER	19615 LIVERPOOL PKWY	CORNELIUS	NC	28031	N	3	1	1
1681504	SAUL	SCHWARZ	608 N ELM ST	HIGH POINT	NC	27282	N	3	3	3
0762202	DAVID	SEALES	1520 MEADOWVIEW DR	N WILKESBORO	NC	28697	N	3	3	1
1720541	CAROL	SENA	201 N EUGENE ST	GREENSBORO	NC	27401	P	1	1	3
0808662	SHEILA	SMALLS	319 PENNY LN	CONCORD	NC	28025	N	3	2	3
0128345	JOHN	SMITH	180 CHARLOIS BLVD	WINSTON SALEM	NC	27103	N	3	3	3

MS_1888

1228104	GEOFFREY	STARR	169 DEER RUN RD	DANVILLE	VA	24540	N	1	1	2
1223883	SHAWN	STEWART	608 N ELM ST	HIGH POINT	NC	27262	N	3	2	1
0800472	THOMAS	SWEASEY	2810 MAPLEWOOD AVE	WINSTONSALEM	NC	27103	N	3	3	3
0043729	CHARLES	TEGELER	281 HEATHERTON WAY	WINSTONSALEM	NC	27104	N	3	3	3
1593177	UMALAKSHM	THOTAKURA	1303 ASHLEYBROOK LN	WINSTONSALEM	NC	27103	P	2	3	3
0798114	FRANCIS	WALSH	3 DUDLEY ST	MARTINSVILLE	VA	24112	N	2	2	1
0733207	CATHERINE	WEYMANN	1910 N CHURCH ST	GREENSBORO	NC	27405	N	1	3	1
0798029	BARRY	WILLIAMS	1800 BETHESDA PL	WINSTONSALEM	NC	27103	P	2	3	3
0795737	JAMES	WILLIFORD	600 GREEN VALLEY RD	GREENSBORO	NC	27408	P	3	3	3
0823387	CHARLES	WILLIS	1910 N CHURCH ST	GREENSBORO	NC	27405	N	3	2	1
0821093	LEANNE	WILLIS	606 N ELM ST	HIGH POINT	NC	27262	N	1	2	2
1693126	GEORGE	WITTENBERG	300 MEDICAL CENTER BLVD	WINSTONSALEM	NC	27167	N	3	3	2
0025591	ELIZABETH	WRIGHT	276 OLD MOCKSVILLE RD	STATESVILLE	NC	28825	N	1	2	3
0107029	CARLO	YUSON	358 FORSYTH MED PK	WNSTN SALEM	NC	27103	N	3	1	3
1218863	KEVIN	ZITNAY	102 MOCKSVILLE AVE	SALISBURY	NC	28144	N	3	3	3

MS_1889

Neuroscience Call Plan 3T02 2002/09 - 2002/12

- 1** This Form is run with MD's from beginning of trimester .
- 2** The first column lists Target MD's. Targets are based on Frozen Target File.
- 3** Columns 3 - 6 represent the Tiers for each MD with a valid NOV ID for Comtan, Exelon, Trileptal and Ritalin LA. If the decile = " ", then it means that this MD is not a target for this product in the Frozen Target list.
- 4** The column listed "Call Goal" is the goal for the Trimester for each MD, Product and Detail Position. If Call Goal equals "0", it means that this MD should have "0" calls for this product in this position.
- 5** The column listed "Total Calls" are empty. You can update this column each time you make a call on the MD for each product and position. Total calls should equal Call Goals at the end of the trimester.

MS_1890

Neuroscience Call Plan 3T02 2002/09 - 2002/12

Tracking the Call Plan

NC1D1B		P1												P2					
		Tier				Comtan		Exelon		Trileptal		Ritalin LA		Comtan		Exelon		Trileptal	
		A P A	L L Z	A C V	A N D	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls
NOV_ID	Last name, first name																		
0796347	MALONE, JOHN	1	1	1		3		3		3		0		3		0		6	
0796434	LATZ, TRACY			1	3	0		0		0		2		0		0		2	
0796474	WHITENER, JACOB			3	3	0		0		0		1		0		0		1	
0797409	NUTT, SUZANNE	2		1		0		0		6		0		6		0		0	
0798933	DIBERT, STEVEN			1	1	0		6		3		0		0		3		6	
0799338	DUBOIS, CRAIG	1	1	1		0		6		3		0		3		0		6	
0808567	ABBASI-FEINBERG, FARIH	3	2			2		3		0		0		3		2		0	
0812740	THOMAS, BARBARA			1	1	0		0		0		2		0		0		2	
0813070	ELLIOTT, HAROLD			3	1	0		0		0		1		0		0		1	
0813215	FARAH, BRIAN			2	3	0		3		0		0		0		0		3	
0814952	DAVENPORT, CHRISTOPHER	3	3			0		1		0		0		0		0		0	
0821093	WILLIS, LEANNE	1	3			0		6		2		0		0		2		6	
0832879	GIHWALA, RAMESH	1	1			0		6		0		0		0		0		6	
0836814	MEHTA, MALTI			3	3	0		0		0		1		0		0		1	
0840834	THOTAKURA, RAJAKUMAR	3	3			0		1		0		0		0		0		1	
0841620	PILLAI, ASHOKKUMA	2	2	1		0		3		5		0		5		0		3	
0845638	DERIVERS, MERCEDES			3	3	0		0		0		1		0		0		1	
0857994	PHAN, THAI	3	2			0		1		0		0		0		0		1	
1154651	GRANGER, MARILYN			2	3	0		0		0		1		0		0		1	
1157418	FITZGERALD, THOMAS	3	1			0		2		0		0		0		0		2	
1215003	GARCHA, TRISHWANT	3	1			0		0		5		0		5		0		0	
1217945	LAUVE, LUCIE			3	3	0		2		2		0		0		2		2	
1223442	LATZ, JOHN			1	2	0		0		0		2		0		0		2	
1223605	SATER, RICHARD			1	2	0		0		0		0		0		2		6	
1223883	STEWART, SHAWN	2	2			0		0		5		0		5		0		0	
1226621	CARROLL, MARK			2	1	0		0		0		1		0		0		1	
1228741	YAPUNDICH, ROBERT	1	1	1		0		6		3		0		3		0		6	
1334453	ACOSTA, ALBIS	1	1	2		0		5		2		0		2		0		6	
1337136	SYNN, JAY	3	3			0		1		0		0		0		0		1	
1343248	ANDERSON, TRAVIS			2	2	0		0		0		1		0		0		1	
1346032	NOFAL, PHILIP			2	1	0		0		0		1		0		0		1	
1346075	PARROTT, JAMES			1		0		0		6		0		0		0		0	
1347337	RUSSELL-HOWARD, PAMELA	2	2			0		0		5		0		5		0		0	
1364434	MUNOZ, RIGARDY			3	1	0		0		0		1		0		0		1	
1571076	DIFINI, JOHN	1	1	1		0		6		3		0		3		0		5	
1575446	MCKEAN, THOMAS			3	2	0		1		0		0		0		0		1	
1582287	MOSEK, ERIC	2	1	2		0		0		5		0		5		0		0	
1588493	MCCLURE, MICHAEL			3	3	0		0		0		1		0		0		1	
1592304	MUTHU, PREM			2	3	0		0		0		1		0		0		1	
1593177	THOTAKURA, UMALAKSHM	3	3			0		1		0		0		0		0		1	
1595472	PETERS, SARAH	1	3			0		6		0		0		0		0		6	
1675151	MUTHU, AMRUTHAVALLI			3	3	0		0		0		1		0		0		1	
1693126	WITTENBERG, GEORGE	3				2		0		0		0		0		0		0	
1720994	MALONEY, EUGENE			2	3	0		0		0		1		0		0		1	
1727733	CALABRIA, RAFAEL	2	1			0		3		0		0		0		0		3	
1732068	KANDT, RAYMOND	3	2			0		0		5		0		0		5		0	
1743381	GREENBERG, RICHARD			1		0		0		6		0		0		0		0	
1865860	THOMAS, DEJUAN			1	1	0		0		0		2		0		0		2	
1875385	APPLEGATE, MICHAEL	1	2			0		5		2		0		0		2		6	
Terr. Total																			

2/10/2004

Call Execution Report, Template

2

MS_1892

Neuroscience Call Plan 3T02 2002/09 - 2002/12

Tracking the Call Plan

NC1D1B		P1												P2											
		Tier				Comtan				Exelon				Ritalin LA				Comtan				Exelon			
		A P A	A L Z	A C V	A N D	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls	Call Goals	Total Calls
0907836	BEY, RICHARD		2	3		0		2		2		2		0		0		2		2		2		2	
0025591	WRIGHT, ELIZABETH		2	2		0		3		4		0		0		0		4		3		4		3	
0042037	RAU, BRUCE		2	3		0		0		0		1		0		0		0		1		0		1	
0060882	MEYER, DAVID		1	1		0		6		3		0		0		0		3		6		3		6	
0060865	MATTOX, JAMES		3	1		0		2		0		0		0		0		0		2		0		2	
0064765	GUDEMAN, STEVEN			2		0		0		5		0		0		0		0		0		0		0	
0071783	MASCENIK, THOMAS		2	2		3		3		2		0		5		3		0		0		0		0	
0085452	MOREWITZ, NANCY			1		0		6		3		0		0		0		3		6		3		6	
0089795	PORTER, JOHN		1	1		0		6		3		0		3		0		0		6		3		6	
0107029	YUSON, CARLO		2	1		0		0		6		0		6		0		6		0		0		0	
0123326	CROWELL, GILES		1	2		0		6		2		0		0		0		2		6		2		6	
0123327	HILL, EDWARD		1	1		0		6		3		0		0		3		0		6		3		6	
0123420	HAWORTH, CHESTER		1	1		0		6		3		0		3		0		0		6		3		6	
0123000	HILL, DENNIS		2	2		0		3		5		0		5		0		5		3		5		3	
0134375	BRANYON, DAVID			2		1		0		0		1		0		0		0		1		0		1	
0171093	CRANDELL, JASON			3		0		0		0		1		0		0		0		0		0		1	
0171099	WEAVER, EDWARD			2		0		0		0		1		0		0		0		1		0		1	
0171109	HEBERT, STEPHEN			1		0		0		0		2		0		0		0		2		0		2	
0171115	GABY, NANCY			2		0		0		0		1		0		0		0		1		0		1	
0171159	SANDERS, STEPHEN			3		0		0		0		1		0		0		0		1		0		1	
0171465	PILLAI, JEYAKUMAR		3	1		0		2		0		0		0		0		0		2		0		2	
0193471	MARCUS, RICHARD		1	1		0		6		3		0		0		0		3		6		3		6	
0204555	ALLEN, DAVID			2		0		0		0		1		0		0		0		1		0		1	
0204598	JACKSON, TRAVIS			1		0		6		2		0		0		0		2		6		2		6	
0204604	MCCAULEY, ROGER		2	2		0		3		0		0		0		0		0		3		0		3	
0204675	FORD, CHARLES			1		0		6		2		0		0		0		2		6		2		6	
0205462	BOYLES, LARRY			1		0		6		2		0		0		0		2		6		2		6	
0429298	MILLER, JOSEPH			1		0		6		2		0		0		0		2		6		2		6	
0438081	MARTIN, PAUL			1		0		6		2		0		0		0		2		6		2		6	
0438256	MARSHALL, WILLIAM			3		0		0		0		1		0		0		0		1		0		1	
0476674	DEAN, JOAN		3	1		0		0		6		0		0		0		6		0		0		0	
0480306	CHANDER, ERNEST		3	2		0		1		0		0		0		0		0		1		0		1	
0684515	HOOVER, KIM			3		0		0		0		1		0		0		0		1		0		1	
0684695	FERARU, ELAINE			1		0		6		2		0		0		0		2		6		2		6	
0685332	MARSHALL, KATHERINE			2		0		0		0		1		0		0		0		1		0		1	
0700833	RUSS, DONALD			2		0		0		0		1		0		0		0		1		0		1	
0705480	THOMPSON, MYRNA			2		0		0		0		1		0		0		0		1		0		1	
0744258	HUNTER, WILLIAM			3		0		0		3		0		0		0		0		3		0		3	
0748466	CRITTENDEN, JEFFREY		3	2		1		2		3		4		0		0		4		5		0		5	
0748551	MENARD, DALE			1		0		6		2		0		0		0		2		6		2		6	
0758737	GODFREY, JOSEPH			3		0		1		0		0		0		0		0		1		0		1	
0760366	SCHROEDER, KARL			2		0		0		0		1		0		0		0		1		0		1	
0762202	SEALES, DAVID		2	3		0		3		0		3		0		3		0		3		0		3	
0764107	MIEDEN, GREGORY			1		0		6		2		0		0		0		2		6		2		6	
0768772	GAFFNEY, KEVIN		2	2		0		3		4		0		4		0		0		3		0		3	
0778885	DOWNES, DAVID			1		0		6		0		0		0		0		0		6		0		6	
0779129	HUNT, CHRISTOPHER			3		0		2		2		0		0		0		2		2		0		2	
0780837	SCHNEIDER, LORI		1	2		0		3		4		0		4		0		0		3		0		3	
0785950	KIRLEY, STEPHEN			3		0		1		0		0		0		0		0		1		0		1	
0798029	WILLIAMS, BARRY			1		0		6		0		0		0		0		0		6		0		6	
0798053	CREQUE, HALIMENA			3		0		1		0		0		0		0		0		1		0		1	

2/10/2004

Call Execution Report, Template

1

MS_1891

Neuroscience Call Plan 3T02 2002/09 - 2002/12

Tracking the Call Plan

NC1D1B

		Tier				P1								P2							
						Comtan		Exelon		Trileptal		Ritalin LA		Comtan		Exelon		Trileptal			
NOV_ID	Last name, first name	A P A	A L Z	A C V	A N D	Call goals	Total Calls	Call goals	Total Calls	Call goals	Total Calls	Call goals	Total Calls	Call goals	Total Calls	Call goals	Total Calls	Call goals	Total Calls	Call goals	Total Calls

NC1D1B

PHYSICIAN_NAME	NOVID	ADDRESS	CITY	STATE	ZIP	SPECIALTY	CTN_TGT	EXL_TGT	TPL_TGT	CTNTIER	EXLTIER	TPLTIER	CTN_P1_CALL	CTN_P2_CALL	EXL_P1_CALL	EXL_P2_CALL	TPL_P1_CALL	TPL_P2_CALL
APPLEGATE, MICHAEL	1875395	808 N ELM ST	HIGH POINT	NC	27282 N			EXL	TPL	1	2		0	0	0	0	2	6
ATWELL, PHYLIS	0437527	HIV	BOONE	NC	28607 P			TPL		3	N		0	0	1	0	0	1
BELL, WILLIAM	0450702	300 MEDICAL CENTER BLVD	WINSTON-SALEM	NC	27157 N			TPL			2		0	0	0	0	5	0
BRAUNSTEIN, ANDREW	1862123	124 PROFESSIONAL PARK	MOORESVILLE	NC	28117 N			TPL			3		0	0	0	0	1	0
BROGAN, MARLENE	1346453	1562 UNION RD	GASTONIA	NC	28054 P			EXL	TPL	3	N		0	0	1	0	0	1
BURGESS, THERESA	0466872	12308 PO BOX	WINSTON-SALEM	NC	27117 P			EXL	TPL	3	N		0	0	1	0	0	1
CALABRIA, RAFAEL	1727733	238 WILMOT DR	GASTONIA	NC	28054 P			EXL	TPL	2	1		0	0	5	0	0	5
CHANDER, ERNEST	0480305	409 WOODBRIAR TRL	GASTONIA	NC	28056 P			EXL	TPL	3	2		0	0	2	0	0	2
CROWELL, GILES	0128325	175 KIMEL PARK DR	WINSTON-SALEM	NC	27103 N			EXL	TPL	1	2		0	0	8	2	2	6
DURLING, CTIS	0823369	3333 BROOKVIEW HILLS B	WINSTON-SALEM	NC	27103 N			TPL			3		0	0	0	0	1	0
DAVENPORT, CHRISTOPHER	0814962	24 2ND AVE NE	HICKORY	NC	28601 P			EXL	TPL	3	2		0	0	5	0	0	2
DAVIS, CHARLES	1582058	1120 FAIRGROVE CHURCH RD	HICKORY	NC	28602 P			EXL	TPL	2	N		0	0	5	0	0	5
DIBERT, STEVEN	0796833	2355 COURT DR	GASTONIA	NC	28054 H			EXL	TPL	1	1		0	0	5	3	3	6
DOWNES, DAVID	0778685	1120 FAIRGROVE CHURCH RD	HICKORY	NC	28602 P			EXL	TPL	1	N		0	0	5	0	0	6
FARAH, BRIAN	0613215	BLVD DR	HIGH POINT	NC	27262 P			EXL	TPL	1	3		0	0	5	0	0	6
FITZGERALD, THOMAS	1157416	17505 W CATAWBA AVE	CORNELIUS	NC	28031 P			EXL	TPL	3	1		0	0	2	0	0	2
FORD, CHARLES	0204675	624 QUAKER LN	HIGH POINT	NC	27262 N			EXL	TPL	1	2		0	0	5	2	2	6
FREUND, VICTOR	1829404	606 N ELM ST	HIGH POINT	NC	27262 N			TPL			3		0	0	0	0	1	0
GIHWALA, RAMESH	0832879	1511 PLANTATION TRL	GASTONIA	NC	28056 P			EXL	TPL	1	1		0	0	5	0	0	8
GLAZIER, STEVEN	0743727	MEDICAL CTR	WINSTON-SALEM	NC	27157 N			TPL			3		0	0	0	0	1	0
GODFREY, JOSEPH	0759737	2544 COURT DR	GASTONIA	NC	28054 P			EXL	TPL	3	3		0	0	1	0	0	1
GOOD, DAVID	0469051	1854 RUNNYMEADE RD	WINSTON-SALEM	NC	27104 N			TPL			3		0	0	0	0	1	0
GREENBERG, RICHARD	1743381	2555 COURT DR	GASTONIA	NC	28054 N			TPL			2		0	0	0	0	5	0
GREENBERG, JASON	0811050	131 MILLER ST	WINSTON-SALEM	NC	27103 N			TPL			3		0	0	0	0	1	0
GUDEMAN, STEVEN	0647555	2555 COURT DR	GASTONIA	NC	28054 N			TPL			3		0	0	0	0	5	0
HEBERT, STEPHEN	0717139	2990 BETHESDA PL	WINSTON-SALEM	NC	27103 P			EXL	TPL	3	1		0	0	1	0	0	1
HILL, DENNIS	3129030	911 W HENDERSON ST	SALISBURY	NC	28144 N			EXL	TPL	1	1		0	0	6	3	3	6
HUNTER, WILLIAM	0744258	2555 COURT DR	GASTONIA	NC	28054 N			TPL			3		0	0	0	0	4	0
HUSSEY, MICHAEL	0485047	606 N ELM ST	HIGH POINT	NC	27262 N			TPL			3		0	0	0	0	1	0
HYUN, DONG	1580587	3333 BROOKVIEW HILLS BLVD	WINSTON-SALEM	NC	27103 N			TPL			2		0	0	0	0	5	0
JACKSON, TRAVIS	0204598	175 KIMEL PARK DR	WINSTON-SALEM	NC	27103 N			EXL	TPL	1	2		0	0	5	2	2	6
JONES, EDWARD	0437358	205 OLD LEXINGTON RD	THOMASVILLE	NC	27360 P			EXL	TPL	3	3		0	0	1	0	0	1
KANDT, RAYMOND	1732088	606 N ELM ST	HIGH POINT	NC	27262 N			EXL	TPL	3	2		0	0	2	4	4	2
KARWAN, SUKHENDER	1593385	200 BUSINESS PARK DR	ELKIN	NC	28621 P			EXL	TPL	3	1		0	0	2	0	0	2
KIRLEY, STEPHEN	0795950	2554 LWSVILLE CLMNS RD	CLEMMONS	NC	27012 P			EXL	TPL	2	2		0	0	5	0	0	5
LATZ, JOHN	1223442	116 S MAIN ST	MOORESVILLE	NC	28115 P			EXL	TPL	3	1		0	0	1	0	0	1
LYERLY, MARK	0739562	138 POLO DR	SALISBURY	NC	28144 N			TPL			3		0	0	0	0	1	0
MARCHESE, MARK	0700587	1889 TATE BLVD SE	HICKORY	NC	28602 N			TPL			3		0	0	0	0	1	0
MARSHALL, KATHERINE	0553389	725 N HIGHLAND AVE	WINSTON-SALEM	NC	27101 P			EXL	TPL	3	2		0	0	1	0	0	1
MATTOX, JAMES	0808065	2990 BETHESDA PL	WINSTON-SALEM	NC	27103 P			EXL	TPL	3	1		0	0	1	0	0	1
MCCAULEY, ROGER	0204604	175 KIMEL PARK DR	WINSTON-SALEM	NC	27103 P			EXL	TPL	2	2		0	0	5	0	0	5
MCCLOSKEY, SCOTT	0205457	415 N CENTER ST	HICKORY	NC	28601 N			TPL			3		0	0	0	0	1	0
MCKEAN, THOMAS	1575446	24 2ND AVE N	HICKORY	NC	28601 P			EXL	TPL	3	2		0	0	1	0	0	1
MENARD, DALE	0748551	1885 TATE BLVD SE	HICKORY	NC	28602 N			EXL	TPL	1	2		0	0	5	2	2	6
MEYER, DAVID	0080962	175 KIMEL PARK DR	WINSTON-SALEM	NC	27109 N			EXL	TPL	1	1		0	0	5	3	3	6
MIEDEN, GREGORY	0794107	808 N ELM ST	HIGH POINT	NC	27262 N			EXL	TPL	1	2		0	0	5	2	2	6
MILLER, JOSEPH	0429268	808 N ELM ST	HIGH POINT	NC	27262 N			EXL	TPL	1	2		0	0	5	2	2	6
MILLER, PETER	0812873	415 N CENTER ST	HICKORY	NC	28601 N			TPL			3		0	0	0	0	1	0
MOREWITZ, NANCY	0086452	812 32ND ST SE	CONOVER	NC	28613 N			EXL	TPL	1	1		0	0	5	3	3	6
PARROTT, JAMES	1348076	1885 TATE BLVD SE	HICKORY	NC	28602 N			TPL			1		0	0	0	0	8	0
PETERS, SARAH	1585472	24 2ND AVE NE	HICKORY	NC	28601 P			EXL	TPL	1	2		0	0	5	0	0	6
PHAN, THAI	0857954	1396 OLD MILL CIR	WINSTON-SALEM	NC	27103 P			EXL	TPL	3	2		0	0	2	0	0	2
PILLAI, ASHOKKUMA	0841620	238 WILMOT DR	GASTONIA	NC	28054 N			EXL	TPL	1	1		0	0	5	3	3	6
PILLAI, JEYAKUMAR	0171465	1307 HEATHERLOCH DR	GASTONIA	NC	28054 P			EXL	TPL	3	1		0	0	1	0	0	1
REIFLER, BURTON	1666789	MEDICAL CENTER BLVD	WINSTON-SALEM	NC	27157 P			EXL			3		0	0	1	0	0	0
ROSENQUIST, PETER	0778875	MEDICAL CENTER BLVD	WINSTON-SALEM	NC	27157 P			EXL	TPL	3	N		0	0	1	0	0	1
ROY, RANJAN	0761300	1616 WILTSHIRE RD	SALISBURY	NC	28144 N			TPL			3		0	0	0	0	1	0
SATER, RICHARD	1223805	624 QUAKER LN	HIGH POINT	NC	27262 N			EXL	TPL	1	2		0	0	5	2	2	6
SHUKLA, VIKRAM	1740893	N DATA SUPPLIED	GASTONIA	NC	28052 P			EXL	TPL	3	N		0	0	0	0	0	2
SHVEET, RAYMOND	0086219	226 WILMOT DR	GASTONIA	NC	28054 N			EXL	TPL	3	3		0	0	0	0	1	0
SYNN, JAY	1337436	24 2ND AVE N	HICKORY	NC	28601 P			EXL	TPL	3	2		0	0	2	0	0	2
THOTAKURA, UMALAKSHM	1595177	1303 ASHLEYBROOK LN	WINSTON-SALEM	NC	27103 P			EXL	TPL	2	2		0	0	5	0	0	5
WILLIAMS, BARRY	0798029	1800 BETHESDA PL	WINSTON-SALEM	NC	27103 P			EXL	TPL	1	3		0	0	5	0	0	5
WILUS, LEANNE	0821093	809 N ELM ST	HIGH POINT	NC	27262 N			EXL	TPL	1	2		0	0	5	2	2	6
WILSON, JOHN	0728277	ROSEMARY GRAY SCHOOL OF	WINSTON-SALEM	NC	27157 P			TPL			3		5	5	5	1	5	5
YAPUNDICH, ROBERT	1229741	1995 TATE BLVD SE	HICKORY	NC	28602 N			EXL	TPL	1	1		0	0	5	3	3	6
ACOSTA, ALBIS	1334463	800 COX RD	GASTONIA	NC	28054 N		CTN	EXL	TPL	1	1		0	2	5	0	2	5
DIFINI, JOHN	1571078	500 COX RD	GASTONIA	NC	28054 N		CTN	EXL	TPL	1	1		0	3	5	0	3	6

Page 1

MS_1821

NC1D1B

DUBOIS, CRAIG	0799938 124 PROFESSIONAL PARK	MOORESVILLE NC	28117 N	CTN	EXL	TPL	1	1	1	0	3	6	0	3	6
HAWORTH, CHESTER	0128420 624 QUAKER LN	HIGH POINT NC	27262 N	CTN	EXL	TPL	1	1	1	0	3	6	0	3	6
HILL, EDWARD	0128327 3333 BROOKVIEW HILLS BLVD	WINSTON SALEM NC	27103 N	CTN	EXL	TPL	1	1	1	0	3	6	0	3	6
MALONE, JOHN	0796347 423 S SOUTH ST	MOUNT AIRY NC	27030 N	CTN	EXL	TPL	1	1	1	0	3	6	0	3	6
MARCUS, RICHARD	0193471 1895 TATE BLVD SE	HICKORY NC	28602 N	CTN	EXL	TPL	1	1	1	0	3	6	0	3	6
MASCENIK, THOMAS	0071763 660 PARKWOOD MEDICAL PARK	ELKIN NC	28621 N	CTN	EXL	TPL	1	3	3	0	3	2	0	3	2
PORTER, JOHN	0089795 3333 BROOKVIEW HILLS BLVD	WINSTON SALEM NC	27103 N	CTN	EXL	TPL	1	1	1	0	3	6	0	3	6
SCHNEIDER, LORI	0790837 20476 CHARTWELL CTR DR A	DAVIDSON NC	28038 N	CTN	EXL	TPL	1	2	2	0	2	5	0	2	5
SEALES, DAVID	0762202 235 JEFFERSON ST	N WILKESBORO NC	28659 N	CTN	EXL	TPL	1	3	3	4	3	2	0	3	6
STEWART, SHAWN	1223683 808 N ELM ST	HIGH POINT NC	27262 N	CTN	EXL	TPL	1	3	2	0	4	2	0	4	2
BOYLES, LARRY	0205482 420 N CENTER ST	HICKORY NC	28601 N	CTN	EXL	TPL	2	2	2	0	2	5	0	3	2
CRITTENDEN, JEFFREY	0749486 403 SHADOWLINE DR	BOONE NC	28607 N	CTN	EXL	TPL	2	1	2	1	0	6	3	2	6
GARCHA, TRISHWANT	1215003 124 SUNSET HILL DR	STATESVILLE NC	28625 N	CTN	EXL	TPL	2	3	1	0	5	1	0	5	1
MCADAMS, SUZANNE	0743026 695 STATE FARM RD	BOONE NC	28607 N	CTN	EXL	TPL	2	1	3	2	0	6	3	1	6
MOSER, ERIC	1562287 624 QUAKER LN	HIGH POINT NC	27262 N	CTN	EXL	TPL	2	3	2	0	3	3	0	3	3
NUTT, SUZANNE	0717409 2556 COURT DR	GASTONIA NC	28054 N	CTN	EXL	TPL	2	3	1	0	5	1	0	5	1
POTTER, CHRISTOPHER	1869220 1985 TATE BLVD SE	HICKORY NC	28602 N	CTN	EXL	TPL	2	3	2	0	4	1	0	4	1
RUSSELL-HOWARD, PAMELA	1347337 1985 TATE BLVD SE	HICKORY NC	28602 N	CTN	EXL	TPL	2	3	1	0	4	3	0	4	3
WITTENBERG, GEORGE	1893126 300 MEDICAL CENTER BLVD	WINSTON SALEM NC	27157 N	CTN	EXL	TPL	2	3	1	0	1	1	0	0	0
YUSON, CARLO	0107029 358 BETHESDA RD	WINSTON SALEM NC	27103 N	CTN	EXL	TPL	2	2	1	0	3	5	0	3	5
ABBASI-FEINBERG, FARHA	0808867 900 COX RD	GASTONIA NC	28054 N	CTN	EXL	TPL	3	3	N	2	0	2	2	0	2
DEAN, JOAN	0478874 3726 VEST MILL RD	WINSTON SALEM NC	27103 N	CTN	EXL	TPL	3	3	1	0	4	3	0	4	3
FERARU, ELAINE	0684055 624 QUAKER LN	HIGH POINT NC	27262 N	CTN	EXL	TPL	3	1	2	0	0	6	3	2	6
GAFFNEY, KEVIN	0768772 011 W HENDERSON ST	SALISBURY NC	28144 N	CTN	EXL	TPL	3	3	2	0	3	3	0	3	3
MARTIN, PAUL	0438061 3314 HEALY DR	WINSTON SALEM NC	27103 N	CTN	EXL	TPL	3	1	3	2	0	6	3	1	6
WRIGHT, ELIZABETH	0025591 1718 PO BOX	STATESVILLE NC	28687 N	CTN	EXL	TPL	3	2	2	2	0	5	2	2	7
ROSENBERG, JASON	2140646 1 MEDICAL CTR	WINSTON SALEM NC	27157 N	CTN	EXL	TPL	N		3	0	1	0	0	1	0

Page 2

MS_1822

Resource Guide

**NEUROSCIENCE
NEW HIRE
EXPANSION**

 **EXELON®**

(rivastigmine tartrate)

1.5, 3.0, 4.5, 6.0 mg Capsules
2 mg/ml Oral Solution

TRILEPTAL® 
(oxcarbazepine)

150-300-600 mg tablets 300 mg/5 mL oral suspension

COMTan®
(entacapone) tablets

 **NOVARTIS**

**2002
Training
Meeting**

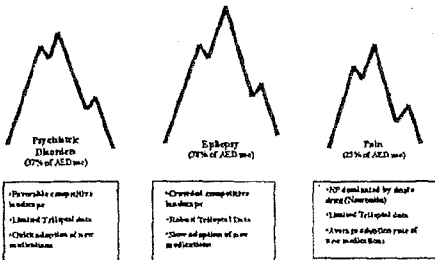
February 12
through
March 1
Hanover,
New Jersey

MS_0618

Trileptal Marketing Presentation

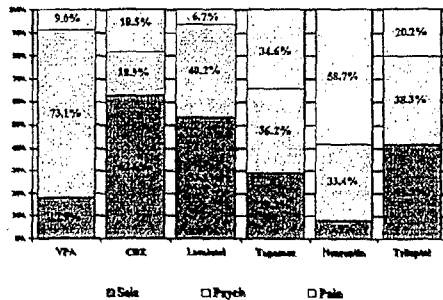
Pankaj Dave
Associate Director, Trileptal Marketing

U.S. Market for AEDs: 46MM Rxs YTD, growing at 13% per year



2

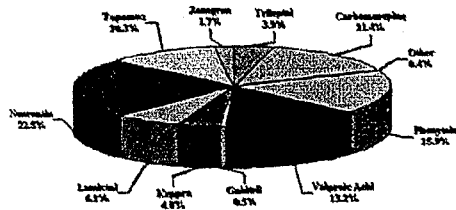
Selected Anticonvulsant Prescribing by Use November 2001 YTD



3

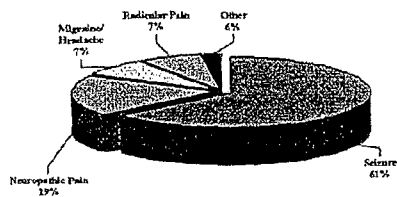
Pain
Psych
(Bipolar)
Seizure

AED Market NRx Share Among Neurologists
12/22/01-12/28/01

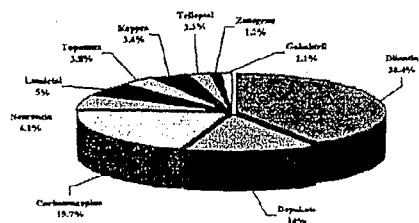


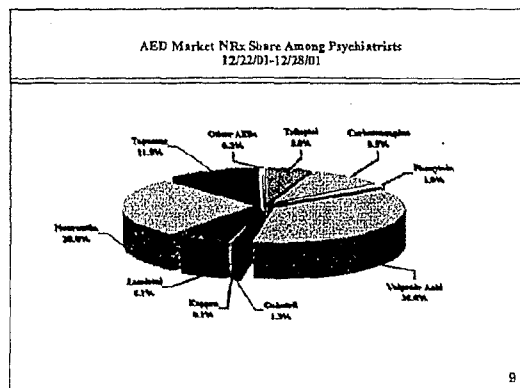
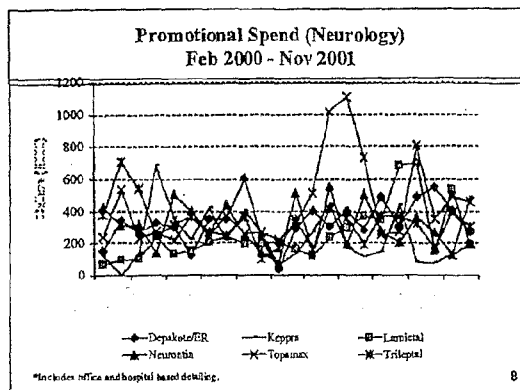
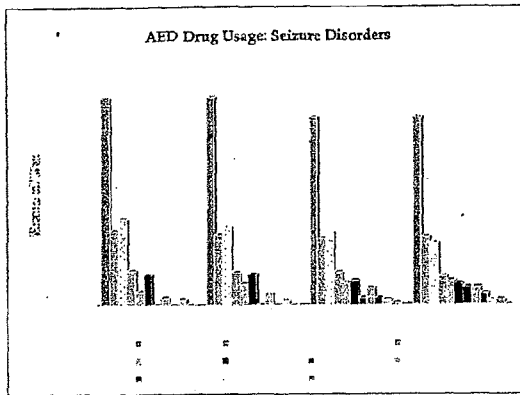
4

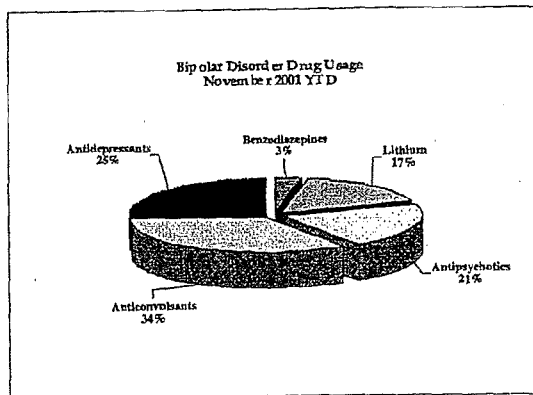
AED Uses in Neurology
November 2001 YTD

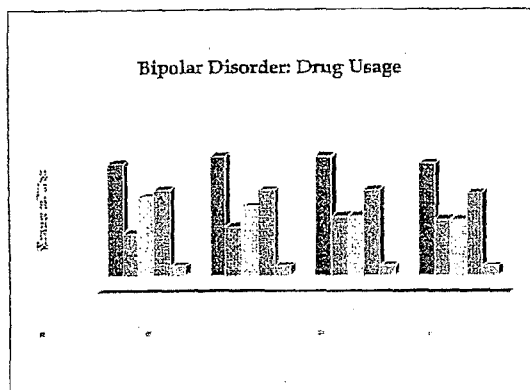


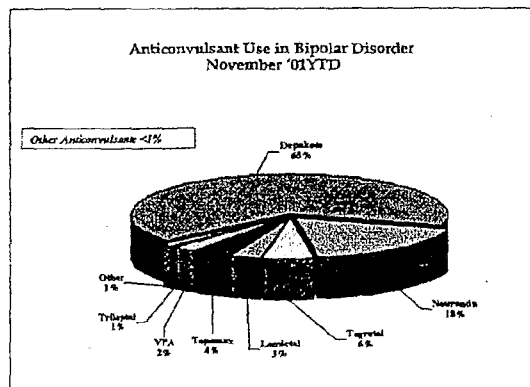
AED Share of Usage in Seizure Disorders
November 2001 YTD

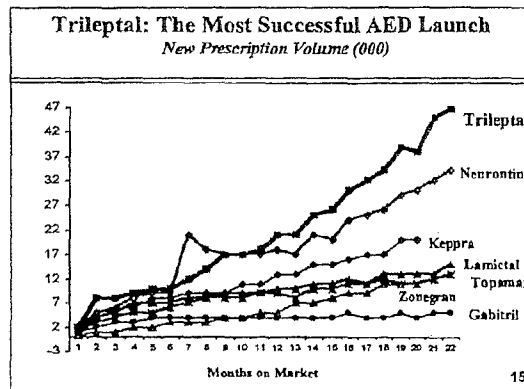
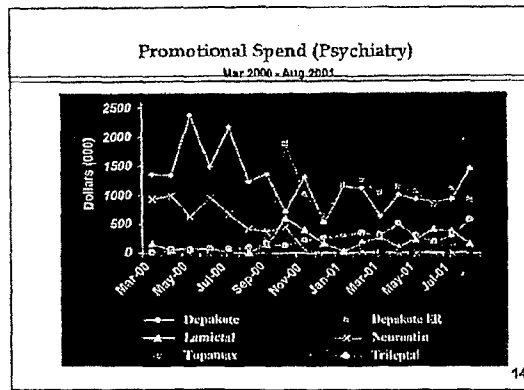
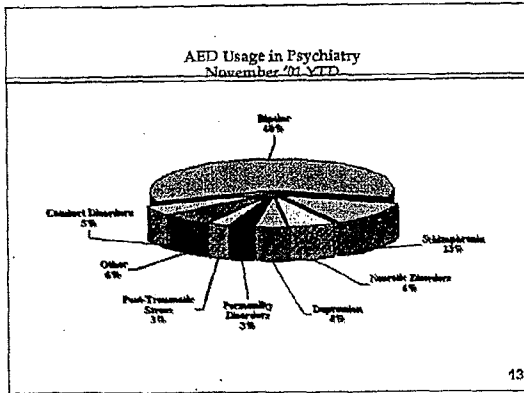


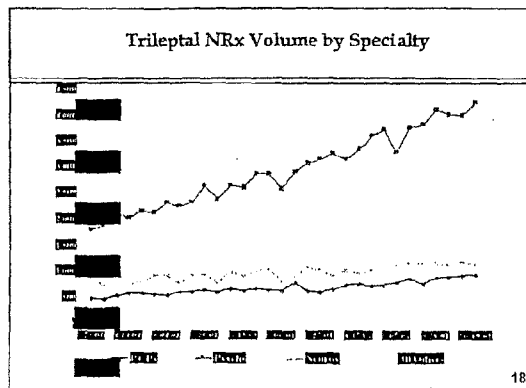
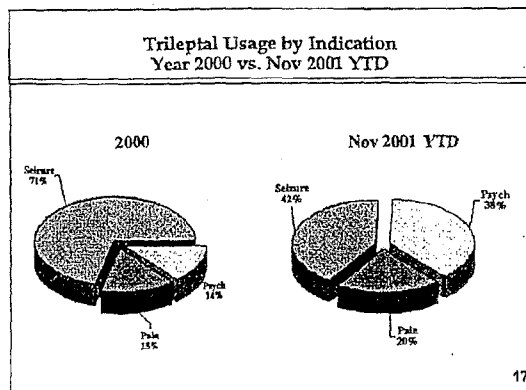
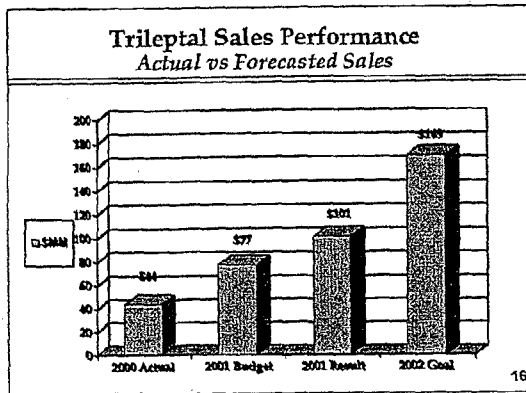


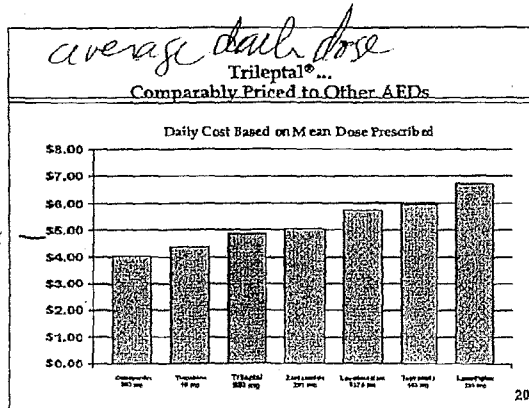
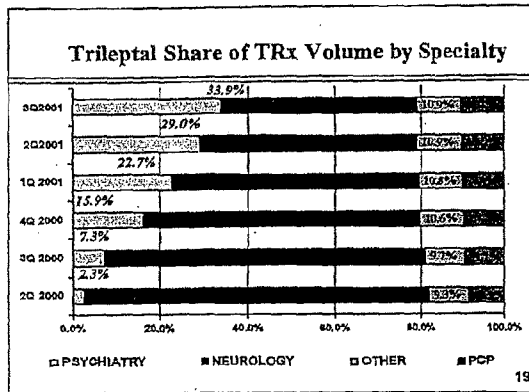












Trileptal Positioning

Trileptal is the preferred AED because it delivers the best overall package of clinical benefits (efficacy, safety, tolerability, and ease of use)

Trileptal Key Selling Messages

- Trileptal builds on the benefits of carbamazepine by offering many important pharmacologic and clinical distinctions
- Trileptal delivers effective seizure control as a monotherapy in adults and as an adjunctive therapy in adults and children
- Trileptal has a favorable safety profile with few drug interactions and no black box warnings
- Trileptal is well tolerated with no weight gain or cosmetic side effects
- Trileptal is easy to dose and manage with linear kinetics and no monitoring requirements for most patients

22

Trileptal Position Selling Strategy: *Focus on Product Profile Comparison versus CBZ*

- Neurologists and Psychiatrists are very familiar with CBZ
 - Favorable impression of efficacy
 - Concern over drug interactions, monitoring requirements, tolerability, and overall safety
- Trileptal is a keto analogue of CBZ with a very favorable product profile relative to CBZ and other first-line anticonvulsants
- An effective product profile comparison is an excellent way to differentiate the two compounds and can be delivered in less than a minute

Important Reminder: Off-label questions can only be answered through Medical Affairs

23

Summary

- The Anticonvulsant market is currently generating 37 million prescriptions per year and is growing at 14% per year
- Anticonvulsant growth continues in neurology; use in psychiatry also key to to class growth
- The Trilepta[®] launch is the most successful launch of an anticonvulsant to date
- Continued growth in both neurology and psychiatry will be key drivers of Trilepta[®] prescription growth in 2002 and beyond
- Welcome aboard!!!

24



Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

MEDICAL INQUIRY ONLY

Confirmation #

--	--	--	--	--	--	--	--	--	--

FOR OFFICE USE ONLY

Inquiry #:

Comp Date:

Representative _____

Title _____

Territory # _____

Voice Mail # _____

DM _____ VM # _____

Date _____

Do not use this form for reporting
Adverse Event(s). Report Adverse
Event(s) on Form FRM-FLDRS007

(Staple business card or please print/type clearly:)

Healthcare

Professional's Name _____

Degree: ☐ MD ☐ DO ☐ DPM ☐ RPH ☐ Other _____

Institution/Office _____

Department _____

Street Address _____

City _____ State _____ Zip _____

Telephone (____) _____ Fax (____) _____

E-Mail _____

Specialty _____

MEDICAL INQUIRY

NAME OF PRODUCT _____

(One product per form – specify question/request):

(Healthcare Professional's Signature — One Name Per Form)

MEDICAL INQUIRY FRM-FLDRS006

(Rep: Send original to Medical Affairs, East Hanover. Retain yellow copy.)

7/00

MS 0000

This copy is intended for internal informational purposes only
and is not intended for distribution to non-Novartis personnel.

Sales Rep. Territory Number: NC1D1B

February 25, 2003

Rigardy Munoz, M.D.
Carolina Treatment Associates
419 Second Street NW
Hickory, NC 28601

Dear Dr. Munoz:

Your Neuroscience Associate, Steve Mc Kee, has forwarded to us your request for information regarding Trileptal® (oxcarbazepine) and its use in the treatment of mania, bipolar, and aggression disorders.

Trileptal® (oxcarbazepine), a 10-keto analogue of carbamazepine (CBZ), is an antiepileptic drug indicated for use as monotherapy or adjunctive therapy for partial seizures in adults and as adjunctive therapy in children ages 4-16 years with epilepsy. Novartis received marketing clearance from the Food and Drug Administration (FDA) on January 14, 2000. In evaluating Trileptal for marketing clearance, the FDA reviewed results from 34 trials and a safety database that included more than 6,900 patients. Trileptal is not indicated for use in the treatment of aggressive, bipolar, and mania disorders and there is no FDA approved dosing regimen.

Aggressive, Bipolar and Mania Disorders

Retrospective reviews of 200 cases by **Reinstein et al. (2002)** (age range 11-83 years) showed positive findings with regards to improvement in manic symptoms in patient who had received oxcarbazepine (OXC) therapy. Of the 200 cases reviewed, 194 showed an improvement in psychiatric symptoms as documented/confirmed by resolution of admission criteria. The admission criteria were not provided. The dose range for OXC was 600-3000mg daily. None of the patients had to discontinue OXC therapy due to dose-related side effects or cognitive/neuropsychiatric adverse events, such as psychomotor slowing, impaired concentration, speech or language problems, somnolence, or fatigue, or coordination abnormalities including ataxia and gait disturbances. Of the 200 cases reviewed, 3 discontinued therapy due to hyponatremia (sodium <125mEq/L) within three days of initiating OXC treatment. Nineteen (19) patients were flagged for drug-drug interaction with their drug regimens. Of these, 3 patients discontinued therapy due to concomitant treatment with oral contraceptives. The other 16 patients all of whom received calcium channel blockers were evaluated for blood pressure irregularities. No significant blood pressure increases were measured and all 16 patients remained on OXC and their calcium channel blockers at the time of discharge.

Nasr and Casper (2002) reviewed the charts of 87 patients (ages 13-72 years) with mood disorders over a 9-month period. Seventy percent of the patients had previously failed to improve on other AEDs, which included clonazepam, valproate, carbamazepine, gabapentin, lamotrigine, and topiramate, or experienced intolerable adverse events. No information was provided on adverse events. Each patient was assessed using a computerized version of MiniSocid and Psychosocial history, SCL-90, visual analogue scale (VAS), Carroll Depression Rating Scale

MS_0009

Rigardy Munoz, M.D.
Hickory, NC 28601

2/25/03
Page 2

(CRDS), and a CGI-Severity of Illness score. The mean dose of oxcarbazepine was 801mg/day (\pm 359mg). The results showed a statistically significant improvement in mean CGI-S score for all patients ($p < 0.0001$). Forty-one (47%) of the patients were rated as "much" to "very much" improved on the CGI-S scale at last observation. Bipolar patients reported significant improvement in their VAS score ($p < 0.03$) and CDRS ($p < 0.06$) compared to unipolar patients. The adverse events experienced by patients included, nausea ($n=3$), weight gain ($n=2$), intolerability ($n=2$), edema ($n=1$), headache ($n=1$), hives/blisters ($n=1$), rash ($n=1$), and sedation ($n=1$). The authors conclude that there is potential for using OXC in the treatment of mood disorders and OXC use in prospective, randomized, placebo, controlled studies are needed for further evaluation of this population.

In a prospective, single-center, open-label trial, **Munoz (2002)** investigated the mood stabilizing effects of OXC as adjunctive therapy in 30 patients (ages 18-65 years) with a DSM-IV diagnosis of bipolar disorder. Of the 28 patients who completed the study, 21 patients were manic and 7 patients were depressed at the time of enrollment. Patients who were receiving active treatment for their manic or depressive state had OXC added to their regimen for 12 weeks. During the titration of OXC, their current medication(s) were tapered if necessary. OXC was initiated at a dose of 300mg and increased to a maximum of 2400mg/day. The primary efficacy measures were the Young Mania Rating Scale (YMRS) and the Hamilton Rating Scale (HAMD). The Scale for Affective Disorders and Schizophrenia (SADS) and the Global Assessment Schedule (GAS) were the other efficacy measures used for overall psychiatric functioning and daily self-reporting of mood, sleep, life events and medications. Responders were defined as manic patients with a $> 50\%$ improvement in YMRS after 3 weeks, or as depressed patients with a 50% improvement in HAMD after 6 weeks. The results of the study showed that of the 21 patients who were manic at the start of the study, 15 patients (71%) responded to OXC with $\geq 50\%$ improvement in YMRS within 3 weeks of starting treatment. Of the 15 patients, 9 remained euthymic, 3 patients relapsed into mania, and 3 became depressed. All 7 patients who were depressed, responded with a $\geq 50\%$ improvement within 6 weeks of starting treatment and remained euthymic. None of the 28 patients who completed the study discontinued OXC therapy due adverse events. Four patients experienced clinically significant hyponatremia (serum Na^+ levels $< 125\text{mEq/L}$), all of whom were receiving concomitant medications. Information on comedications was not provided. Other adverse events experienced were mood related ($n=3$), drowsiness ($n=2$), aspiration pneumonia ($n=1$), asthma ($n=1$), and nausea/vomiting ($n=1$).

In a naturalistic, prospective study, **Reinstein et al. (2001)** evaluated the potential of OXC in the treatment of mania in 42 adults over a ten week period. The study compared efficacy and tolerability between oxcarbazepine (OXC) and divalproex sodium (VA). All 42 subjects were diagnosed with bipolar disorder or schizoaffective disorder and were receiving active treatment of VA; 23 of whom were switched to OXC at baseline. The authors suggest that OXC has comparable efficacy and tolerability to VA in the treatment of mania.

In a letter to the editor, **Teitelbaum (2001)**, discusses a case report on the use of OXC in a 6 year old patient who was diagnosed with bipolar I disorder. The patient had been hospitalized over the previous years due to episodic "out-of-control" behaviors, and had used medications which included lithium carbonate, lamotrigine, valproate, gabapentin, clonidine, risperidone, and quetiapine. OXC was initiated at 150mg twice daily in addition to a regimen of lithium carbonate 150mg three times daily and guanfacine 0.5mg two times daily for 3 months. The author states that the patient experienced "full mood stabilization" within six weeks. Social skills improved to an age-appropriate level, defiant behavior was vastly reduced, and all schoolwork was being completed. No property destruction, no aggression or outbursts were observed after 3 months of maintenance therapy. At 3 months, the lithium dose was reduced to 150mg bid while the guanfacine dosage did not change. Complete symptom remission was maintained for 7 months on OXC therapy without side effects.

MS_0010

Rigardy Munoz, M.D.
Hickory, NC 28601

2/25/03
Page 3

Tavormina (2000), in an open-label, comparative, naturalistic study evaluated the efficacy, safety, and tolerability of OXC versus CBZ as a mood regulator in 13 subjects. All subjects met the DSM-IV diagnostic criteria for bipolar disorder and were assessed by the "Global Assessment Scale" at the beginning of the treatment. CBZ therapy was initiated in nine of the subjects, while 4 were receiving OXC therapy for a duration of 6 weeks. The subjects were monitored periodically for any emergent adverse events. The results showed that all of the subjects obtained a score of > 90 points using the "Global Assessment Scale". All 9 subjects initially receiving CBZ therapy were converted to OXC therapy due to the hepatic, hematologic, cardiac and dermatologic effects experienced with CBZ. Side effects resolved after eight weeks of OXC treatment in these subjects. Details of the side effects were not provided.

Emrich (1990) reviewed the results of double-blind multicenter trials comparing OXC with haloperidol in 42 patients with acute mania, and with lithium in a further 58 acutely manic patients. Psychiatric symptoms were measured using BMRS over 15 days of therapy during which time various drugs were titrated to mean dosages of 2400mg/day or 1400mg/day of OXC (in trials vs haloperidol or lithium respectively), 42mg/day of haloperidol and 1100mg/day of lithium. A decline in mania rating scales values was observed. Although the average improvement with OXC was slower initially, the efficacy was comparable with either haloperidol or lithium by the second week. Haloperidol therapy, however, was associated with a 3.5 fold higher incidence of adverse effects than OXC. The investigator concluded that lithium on the other hand, seemed to be better tolerated than oxcarbazepine.

Greil et al. (1985), in an open clinical trial, selected 13 patients, aged 35-63 years, with bipolar affective disorders (and schizoaffective psychoses in 2 cases). The majority of these patients were lithium non-responders. Nine patients were treated with OXC, dose range 600-1200mg for 2-11 months, while 4 patients were treated with carbamazepine (CBZ), dose range 400-600mg daily for 11-15 months. Despite lithium treatment the patients had suffered from at least one episode per year and 7 of them had experienced 4 or more episodes within the 12 months preceding study. The investigators observed that there was no reduction in frequency of the episodes during treatment with OXC or CBZ. However, there was a reduction in severity of symptoms in individual patients. There was some further evidence of efficacy since further hospitalization could be avoided in 3 of the 13 patients. Adverse effects noted were dizziness, drowsiness, fatigue and ataxia. Polyuria (lithium-induced) was reduced in 2 patients, and 1 patient dropped out after 2 months of OXC therapy due to dizziness, nausea and headache.

Emrich et al. (1984) investigated the use of oxcarbazepine (OXC) and Depakote (VPA) in patients with manic syndrome. In a double-blind controlled design, 5 pts were on VPA and 7 pts ages 17-34 years, were on OXC. The maximal dose ranges for VPA and OXC were 1.8g-3.9g, and 1.8-2.1g respectively. The results showed that efficacy was similar with both compounds. The average reduction in inpatient multidimensional psychiatric scale was 49.6% and 49.9% for VPA and OXC respectively. These effects were statistically significant.

Velikonja et al. (1984) in their open label study with OXC observed a decrease in psychotic symptoms. The open study was carried out in 10 pts with manic syndrome or schizoaffective psychosis. The eleventh patient dropped out because of an exanthema, probably due to OXC. Patients received 900mg of OXC daily in combination with haloperidol. All 10 patients showed a decrease of psychotic symptoms during the three (3) week trial. A positive response to OXC in patients with severe excitement and aggressive psychopathology was noted using the Friedman tests. In a matched control group at the same site, the average haloperidol dose was twice that of the OXC-treated group. It was evident that with OXC, haloperidol could be given at a lower dose to minimize the side effects. No adverse effects were monitored except for one (1) EEG with an increase of slow, generalized theta-waves. No other changes were observed.

Muller and Stoll (1984) conducted two trials with OXC. The first trial was a multicenter pilot study with OXC used in 48 (age 17-61 years) patients with mania. Doses ranged from

MS_0011

Rigardy Munoz, M.D.
Hickory, NC 28601

2/25/03
Page 4

600mg/day to 2100mg/day and in one case 3000mg/day. Good therapeutic results were observed in 83% of the patients. Adverse reactions such as double vision, dizziness, nausea, itching and increased restlessness were mentioned by only 3 patients. The second controlled double-blind clinical trial included 20 patients who were randomly assigned to either OXC or haloperidol. The duration of trial was 2 weeks. Dose range for OXC was 900-1200mg daily and 15-20mg daily for haloperidol. Psychiatric symptoms were measured according to the Bech-Rafaelson Mania Scale (**BMRS**) at Days 1, 3, 7, and 14. The results showed that the final mania scores decreased the same in both groups, but the onset of action seemed to be faster with OXC.

Views and opinions expressed by authors that may have been cited in this letter or listed in a bibliography do not necessarily represent those of Novartis. The use of Novartis products in any manner other than described in the accompanying full prescribing information is not recommended.

We hope this information proves useful. Thank you for your interest in Trileptal® (oxcarbazepine) and for the courtesy extended to your Neuroscience Associate, Steve Mc Kee.

Sincerely,



Alston Coombs Pharm.D.
Medical Information Specialist
Medical Information & Communication

AC:db:852432
Enclosures

MS_0012

Rigardy Munoz, M.D.
Hickory, NC 28601

2/25/03
Page 5

BIBLIOGRAPHY

Emrich HM et al. Action of sodium-valproate and oxcarbazepine in patients with affective disorders. In: Emrich HM et al. eds. *Anticonvulsants in Affective Disorders*. Int Congr Series No. 626. Amsterdam: Excerpta Medica; 1984:45-55.

Emrich HM. Studies with oxcarbazepine (Trileptal) in acute mania. *Int Clin Psychopharmacol*. 1990;5(suppl 1):83-88.

Greil W et al. Prophylactic treatment of affective disorders with carbamazepine and oxcarbazepine: an open clinical trial. In: Pichot P et al. eds. *Psychiatry. The State of the Art. Vol 3: Pharmacopsychiatry*. Proc VII World Congr Psychiatry, July 11-16, 1983; Vienna, Austria. New York: Plenum Press; 1985: 491-494.

Muller AA and Stoll KD. Carbamazepine and oxcarbazepine in the treatment of manic syndromes—studies in Germany. In: Emrich HM et al., eds. *Anticonvulsants in Affective Disorders*. Int Congr Series No. 626. Amsterdam: Excerpta Medica; 1984:139-147.

Munoz RA. Oxcarbazepine for the treatment of bipolar disorder. Paper presented at: 155th Annual Meeting of the American Psychiatric Association; May 18-23, 2002; Philadelphia, PA. Abstract NR479.

Nasr SJ and Casper ML. Oxcarbazepine use in the treatment of mood disorders. Presented at: 155th Annual Meeting of the American Psychiatric Association; May 18-23, 2002; Philadelphia, PA. Abstract NR256.

Reinstein MJ et al. Comparative efficacy and tolerability of oxcarbazepine versus divalproex sodium in the treatment of mania. Paper presented at: Annual Meeting of the American Psychiatric Association; May 5-10, 2001; New Orleans, LA. Abstract.

Reinstein MJ et al. Oxcarbazepine: review of 200 subjects treated for mania with oxcarbazepine in a hospital setting. Presented at: 155th Annual Meeting of the American Psychiatric Association; May 18-23, 2002; Philadelphia, PA. Abstract NR256.

Suppes T et al. Report of the Texas Consensus Conference Panel on Medication Treatment of Bipolar Disorder 2000. *J Clin Psychiatry*. 2002;63(4):288-299.

Tavormina G. Oxcarbazepine as a mood regulator: its efficacy, safety and tolerability versus carbamazepine [abstract]. *Eur Psychiatry*. 2000;15(suppl 2):339s. Abstract P01.70.

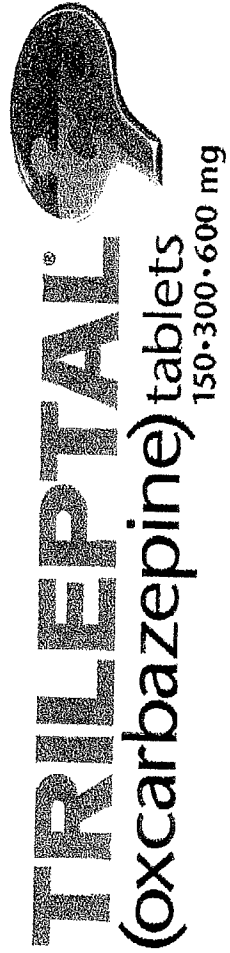
Telitelbaum M. Oxcarbazepine in bipolar disorder. *J Am Acad Child Adolesc Psychiatry*. 2001;40(9):993-994.

Velikonja M and Heinrich K. Effect of oxcarbazepine (CG 47.680) on affective and schizoaffective symptoms—a preliminary report. In: Emrich HM et al., eds. *Anticonvulsants in Affective Disorders*. Int Congr Series No. 626. Amsterdam: Excerpta Medica; 1984:208-210.

Work Group on Bipolar Disorder. Practice guideline for the treatment of patients with bipolar disorder (Revision). *Am J Psychiatry*. 2002;159(4,suppl):1-50.

MS_0013

NPCLSV_LIT01243760

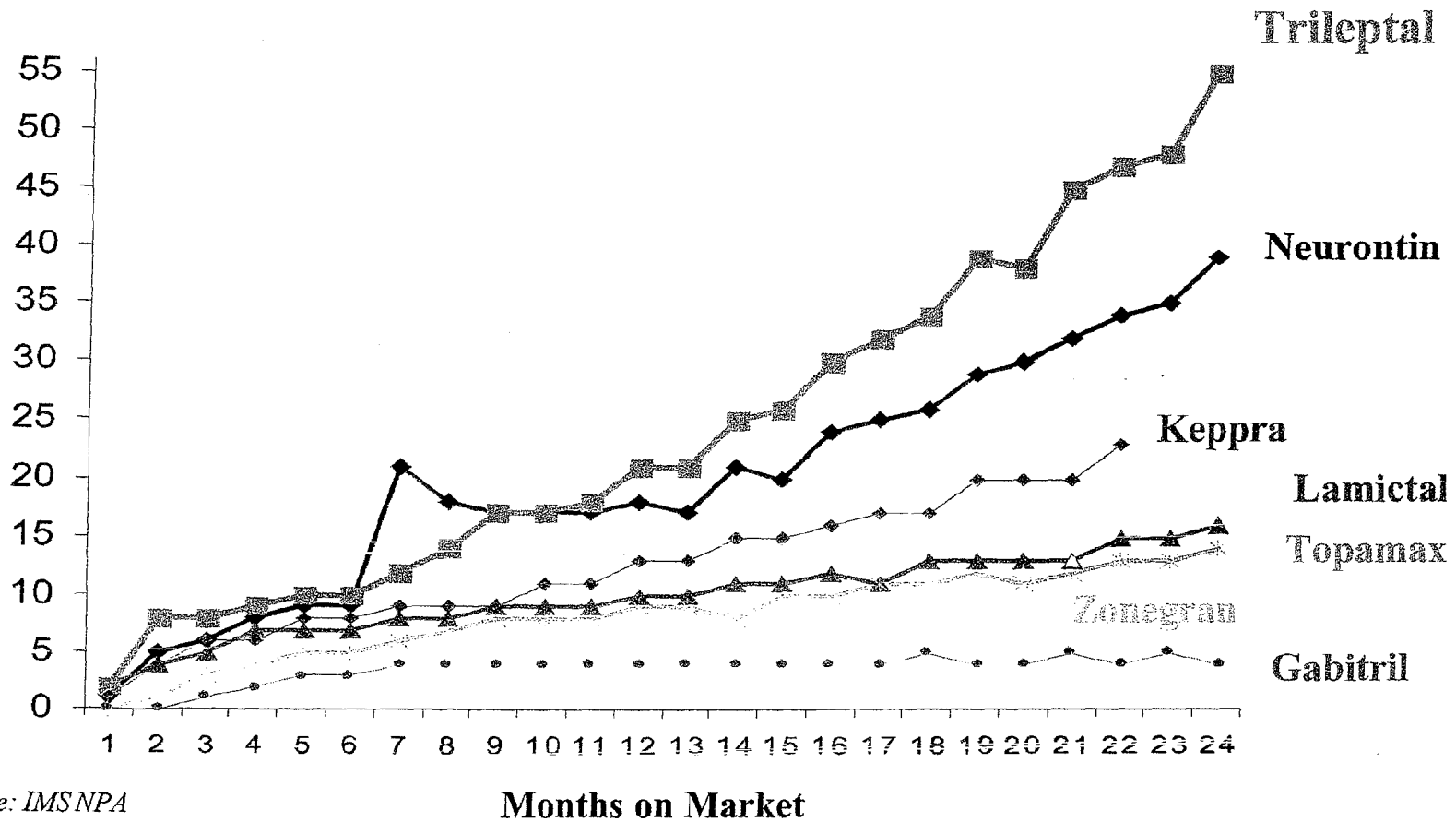


T2 2002 PPM

MS_1825

Trileptal Remains the Most Successful AED Launch

NRx Uptake 2 Years Post launch

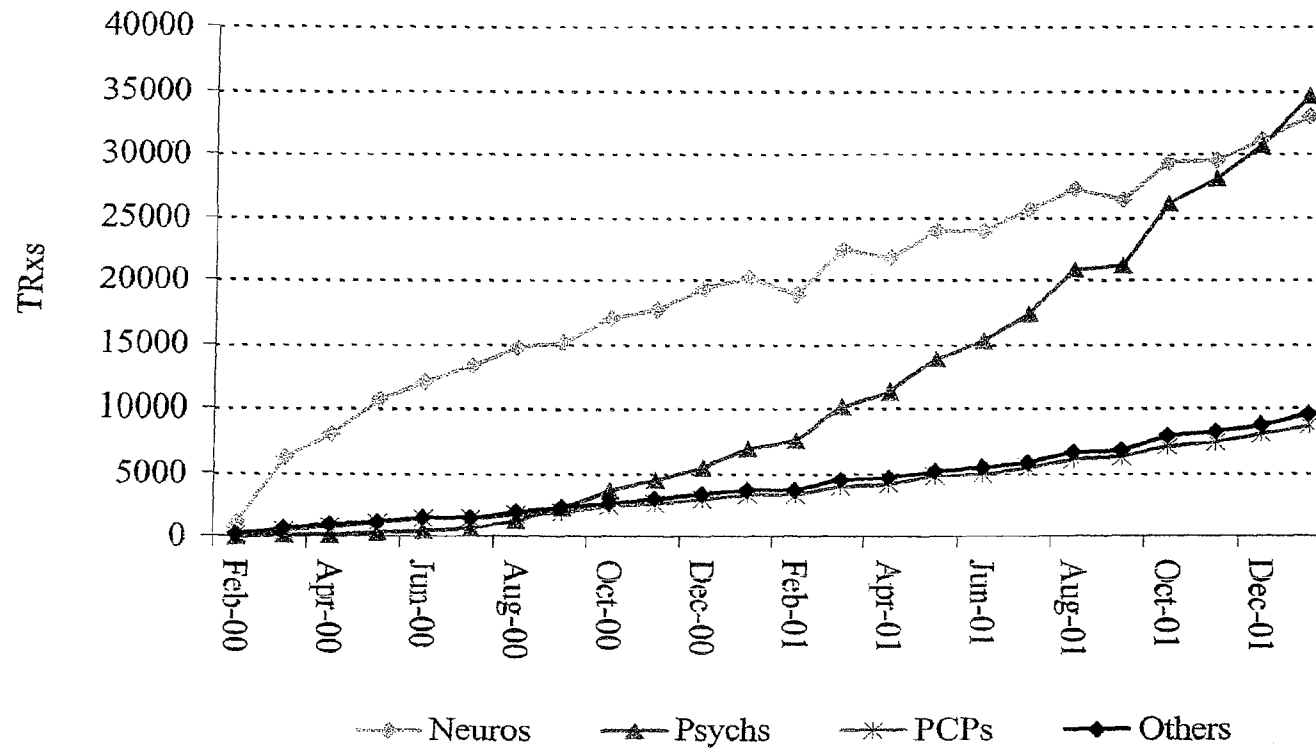


Source: IMS NPA

T. Horich 3-4-02

MS_1829

Trileptal TRx volume by Specialty



- Does not include mail order and "unknown" specialties
- PCPs include GPs, FPs, IMs, and osteopath.

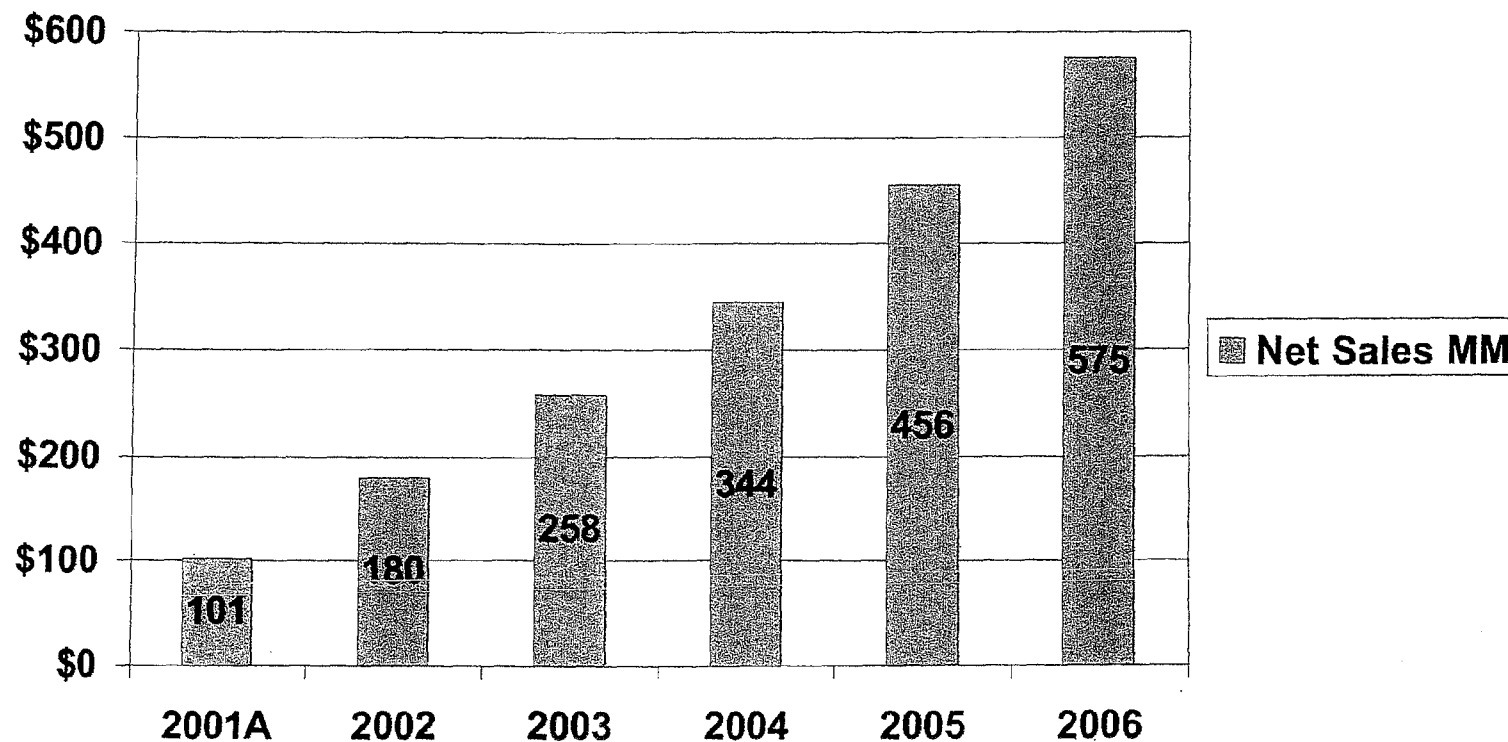
Source: IMS NPA

T. Horich 3-4-02

MS_1830

Trileptal is a Key Growth Driver for Novartis

LE1 5 Year Net Sales Forecast



MS_1831

Reg	(All)
Tgt	(All)
Prod	TPL

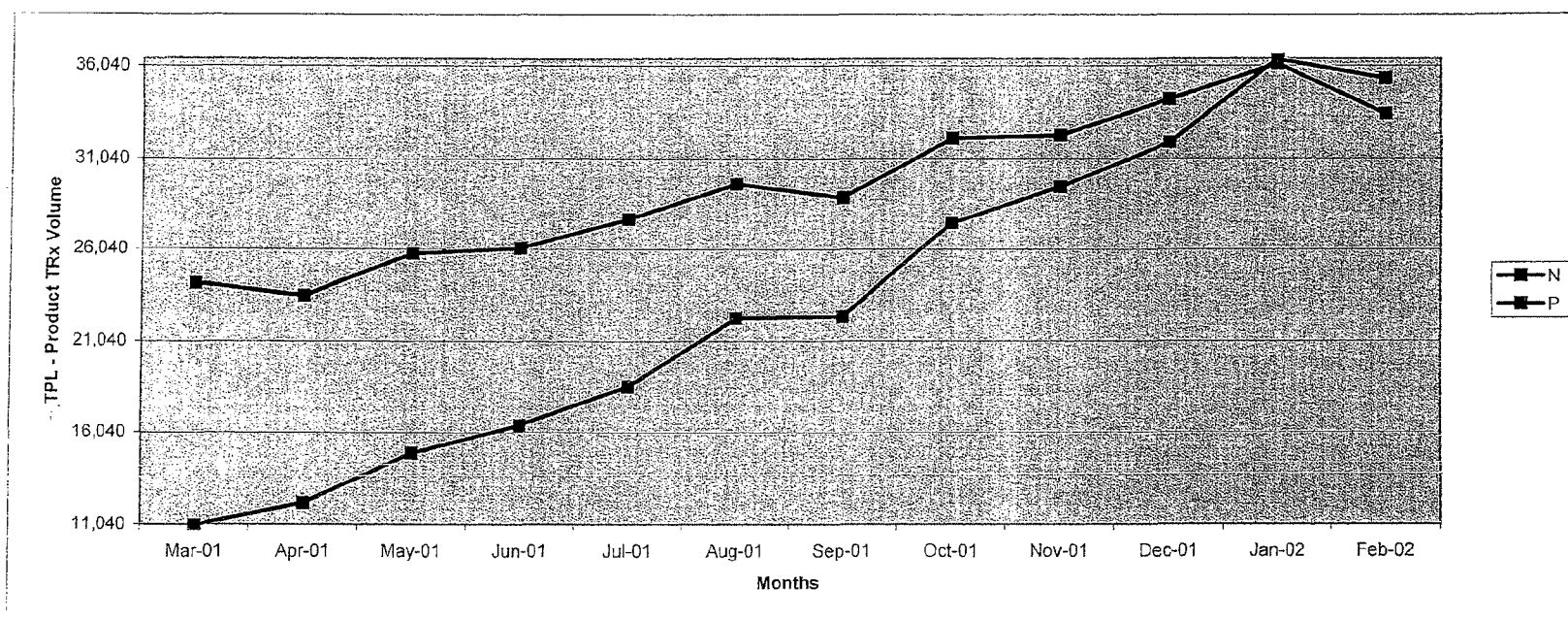
Group By

Specialty

Measure

Product TRx Volume

TPRx	Month											
Spec	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01	Jan-02	Feb-02
N	24,220	23,539	25,810	26,115	27,773	29,690	28,944	32,178	32,348	34,266	36,198	33,490
P	11,045	12,215	14,929	16,450	18,562	22,309	22,406	27,555	29,552	31,972	36,451	35,413
Grand Total	35,265	35,754	40,739	42,565	46,335	51,999	51,350	59,733	61,900	66,238	72,649	68,903



REG	(All)
TGT	(All)
PROD	TPL

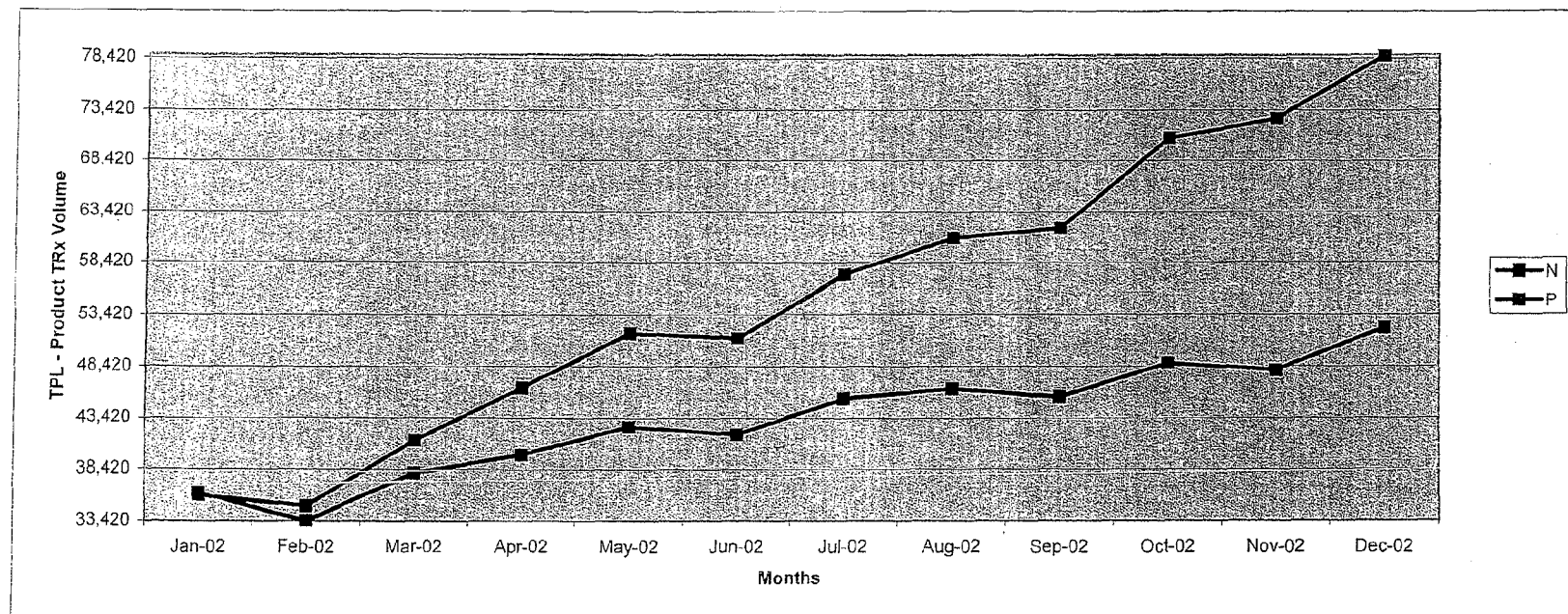
Group By

Specialty

Measure

Product TRx Volume

TPRx	MONTH											
SPEC	Jan-02	Feb-02	Mar-02	Apr-02	May-02	Jun-02	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02
N	36,135	33,421	38,076	39,864	42,622	41,849	45,333	46,303	45,545	48,778	48,123	52,234
P	35,898	34,863	41,276	46,383	51,659	51,202	57,300	60,910	61,873	70,708	72,654	78,777
Grand Total	72,033	68,284	79,352	86,247	94,291	93,051	102,633	107,213	107,418	119,486	120,777	131,011



REG	(All)
TGT	(All)
PROD	TPL

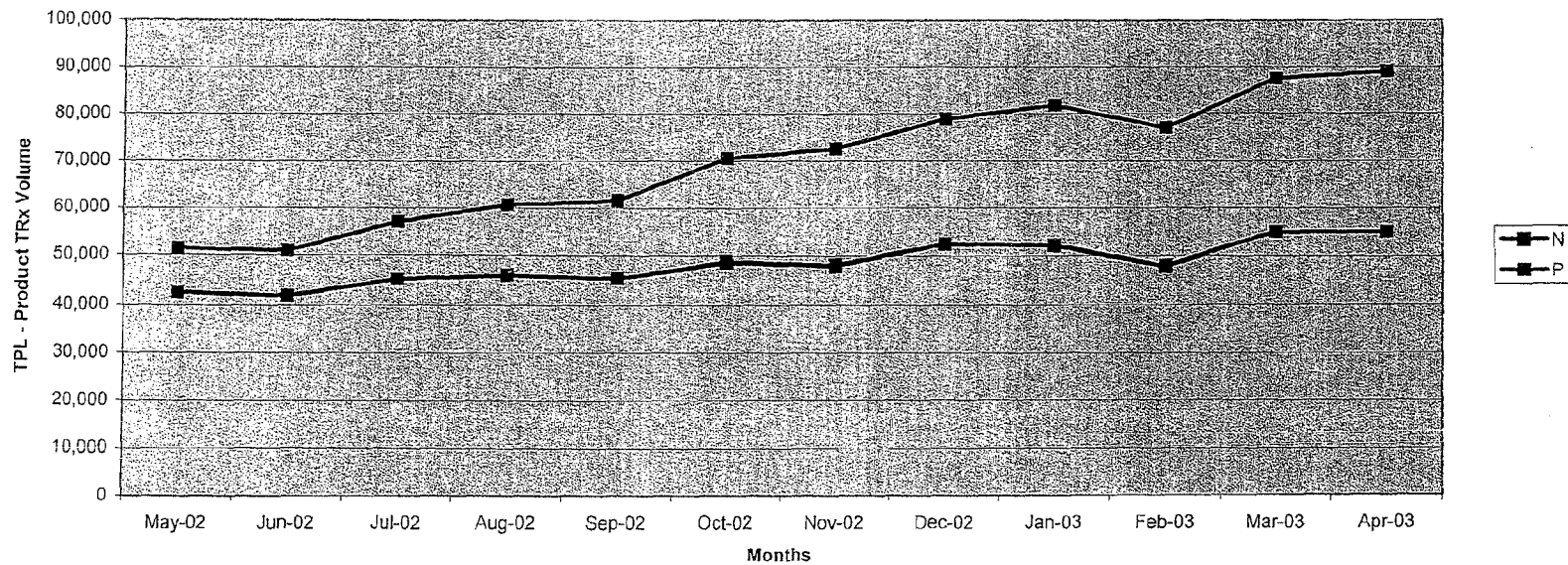
Group By

Specialty

Measure

Product TRx Volume

TPRx	MONTH											
SPEC	May-02	Jun-02	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03
N	42,706	41,968	45,517	46,351	45,696	48,954	48,290	52,438	52,194	48,198	54,996	55,094
P	51,504	51,011	57,134	60,759	61,687	70,691	72,763	79,033	81,983	77,101	87,732	89,185
Grand Total	94,210	92,979	102,651	107,110	107,383	119,645	121,053	131,471	134,177	125,299	142,728	144,279



CUSTOMER SEGMENT TRENDS	
Data Source:	IMS Monthly Projected Physician Level NRx/TRx Data Info One COMPASS Monthly Call Files Current Trimester Frozen Target Lists
General Overview:	These reports contains NRx/TRx share, NRx/TRx volume, P1 Call Volume, and Weighted Details summarized by three different factors: Geography, Physician Specialty, and Target Tier. The files contain 12 month trends ending with the most current month of data.
Data Note:	Physician level data does not include all Mail Order Channels or Zip Level data. May not match Incentive calculations. Universe - The universe of physicians is the same universe of physicians that is used in the monthly Analyzer Reports. Please note that the universe of physicians will always be based on the trimester in which the data month falls. For example, the December, 2001 CST Reports which are released in February, 2002 will be based on the T3 2001 alignment and not the T1 2002 alignment. Deduping - Physicians that are included in the reports are deduped at each level of geography. For example, if a physician is shared between two territories within the same district, that physician would only be counted once in the district sheet. For this reason, volume or share calculations for the same geography may vary slightly between the different worksheets within a report. Alignments - All reports use the alignment codes for the lead sales force within the sales division. This is done to ensure that Hybrid territories are properly represented. Mirrored Territories - For Mirrored territories within a sales division, both rep's names are represented in the reports. For those sales divisions that have partial mirrors, any territories that have a mirror will contain both rep names, and any territories which do not have a mirror will display "VACANT" for the second rep's name.
General Notes:	
Region Sheet	The Grand Total row is the stats for the NATION.
GROUP BY FACTORS	
There are three different factors by which the share, volume, and call data in the file can be summarized. Geography (Region, District, Territory) Physician Specialty (Specific to Product/Sales Force) Target Tier (Specific to Product/Sales Force) Use the "Group By" DropDown Box to select one of the these factors.	
MEASURES	
There are twelve different measures that can be examined. Product NRx - Brand NRx volume Market NRx - Market NRx Volume (same as Class NRx Volume except for Diovan, Foradil, and Lotrel) Class NRx - Class NRx volume Product TRx - Brand TRx volume Market TRx - Market TRx Volume (same as Class TRx Volume except for Diovan, Foradil, and Lotrel) Class TRx - Class TRx volume Details - Weighted Details for the product across all sales forces (P1 + .5*P2 + .05*P3) P1 Calls - First Position (P1) calls for the product across all sales forces. NRx Market Share - Market NRx Share (same as Class NRx Share except for Diovan, Foradil, and Lotrel) NRx Class Share - Class NRx Share TRx Market Share - Market TRx Share (same as Class TRx Share except for Diovan, Foradil, and Lotrel) TRx Class Share - Class TRx Share Use the "Measure" DropDown Box to select one of the these measures.	
Classes, Products, Specialties, and Targets:	
All class share figures take into account all of the products in the Standard Market Definition for each class. Some products may not be displayed in the files, but are included in the class and market share calculations.	
SANDOZ/GEIGY CLASSES AND SPECIALTIES	
Class = (AFO - ORAL ANTI-FUNGAL) LAT - Lamisil SPX - Sporanox + Pulse Pack PLC - Penlac	Class = (ALZ - ALZHEIMER) EXL - Exelon ACP - Aricept RMN - Reminyl
Specialties - AFO Class PCP - Primary Care (FP, GP, IM) D - Dermatology POD - Podiatry A/O - All Other Specialties (No OBGs, PDs, IDs, OTOs, HOs, HEMs, PUDs)	Specialties - ALZ Class PCP - Primary Care (FP, GP, IM) N - Neurology P - Psychiatry A/O - All Other Specialties
Class = (SEC - SELECTED ECZEMA) EDL - Elidel PTP - Protopic ELO - Elocon	
Specialties - SEC Class PCP - Primary Care (FP, GP, IM) D - Dermatology A - Allergists (A, AI, PDA) PD - Pediatricians (PD, PDC, PDE, PDO, PDS, PDT) A/O - All Other Specialties	

CIBA/NOVARTIS CLASSES AND SPECIALTIES	
Class = (AHY - ANTI-HYPERTENSION) DIO+HCT - Diovan+HCT COZ/HYZ - Cozaar/Hyzaar AVA/ALD - Avapro/Avalide Specialties - AHY Class PCP - Primary Care (FP, GP, IM) CV - Cardiovascular (CD, ICE, CDS, NEP, END, DIA) A/O - All Other Specialties	Class = (DIA - ORAL DIABETES) STR - Starlix GPH+GPX - Glucophage+XR ATS+AVD - Actose + Avandia (Glitazones) Specialties - DIA Class PCP - Primary Care (FP, GP, IM) END - Endocrinology (END, DIA) A/O - All Other Specialties
NOVARTIS III/III CLASSES AND SPECIALTIES	
Class = (AHY - ANTI-HYPERTENSION) LTL - Lotrel NRV - Norvasc Specialties - AHY Class PCP - Primary Care (FP, GP, IM) CV - Cardiovascular (CD, ICE, CDS, NEP, END, DIA) A/O - All Other Specialties Class = (AFO - ORAL ANTI-FUNGAL) LAT - Lamisil SPX - Sporanox + Pulse Pack PLC - Penlac Specialties - AFO Class PCP - Primary Care (FP, GP, IM) D - Dermatology POD - Podiatry A/O - All Other Specialties (No CBGs, PDS, IDS, OTOS, HOs, HEMS, PUDs)	Class = (AVO - ORAL ANTI-VIRAL) FVR - Famvir VAL - Valtrax ACYIZOV - Acyclovir+Zovirax Specialties - AVO Class PCP - Primary Care (FP, GP, IM) D - Dermatology A/O - All Other Specialties (No DDSs, OPTs, OPTs or OBGs)
NOVARTIS IV CLASSES AND SPECIALTIES	
Class = (AHY - ANTI-HYPERTENSION) DIO+HCT - Diovan+HCT COZ/HYZ - Cozaar/Hyzaar AVA/ALD - Avapro/Avalide LTL - Lotrel NRV - Norvasc Specialties - AHY Class PCP - Primary Care (FP, GP, IM) CV - Cardiovascular (CD, ICE, CDS, NEP, END, DIA) A/O - All Other Specialties	
CARDIOVASCULAR CLASSES AND SPECIALTIES	
Class = (AHY - ANTI-HYPERTENSION) DIO+HCT - Diovan+HCT COZ/HYZ - Cozaar/Hyzaar AVA/ALD - Avapro/Avalide Specialties - AHY Class CD - Cardiology (CD, CDS, ICE) END - Endocrinology (END, DIA) NEP - Nephrology	Class = (DIA - ORAL DIABETES) STR - Starlix GPH+GPX - Glucophage+XR ATS+AVD - Actose + Avandia (Glitazones) Specialties - DIA Class CD - Cardiology (CD, CDS, ICE) END - Endocrinology (END, DIA) NEP - Nephrology
RESP/SKIN DISEASE CLASSES AND SPECIALTIES	
Class = (ASM - ASTHMA) FOR - Foradil ACH - All Anti-Chol Products SVT+SVD - Serevent+Diskus Specialties - AHY Class PCP - Primary Care (FP, GP, IM) A - Allergists (A, AI, PDA) PD - Pediatricians (PD, PDC, PDE, PDO, PDS, PDT) PUD - Pulmonology (PUD, PDP, PCC) A/O - All Other Specialties Class = (SHA - SHORT ACTING ANALEPTIC) FCL - Focalin RIT - Ritalin MTY - Methylin MPN - Methylphenidate HCL Specialties - AHY Class PCP - Primary Care (FP, GP, IM) PD - Pediatricians (PD, PDC, PDE, PDO, PDS, PDT) A/O - All Other Specialties (No Ns or Ps)	Class = (SEC - SELECTED ECZEMA) EDL - Elidel PTP - Protopic ELO - Elocon Specialties - SEC Class PCP - Primary Care (FP, GP, IM) D - Dermatology A - Allergists (A, AI, PDA) PD - Pediatricians (PD, PDC, PDE, PDO, PDS, PDT) A/O - All Other Specialties
NEUROSCIENCE III/III CLASSES AND SPECIALTIES	
Class = (ACV - ANTI-CONVULSANT) TPL - Trioplel NRT - Neurontin TGR+OTH - Tegratol+Tegretol XR+Carbatrol+Carbamazapine	Class = (ALZ - ALZHEIMER) EXL - Exelon ACP - Aricept RMN - Reminyl

Specialties - ACV Class N - Neurology P - Psychiatry		Specialties - ALZ Class N - Neurology P - Psychiatry	
NEUROSCIENCE III CLASSES AND SPECIALTIES			
Class = (APA - ANTI-PARKINSON) CTN - Comtan MIR - Mirapex SMT+GEN - Sinemet+Sinemet CR+Gen Sinemet+Gen Sinemet CR			
Specialties - APA Class N - Neurology			
NEUROSCIENCE IV CLASSES AND SPECIALTIES			
Class = (SHA - SHORT ACTING ANALEPTIC) FCL - Focalin RIT - Ritalin MTY - Methylin MPN - Methylphenidate HCL			
Specialties - AHY Class P - Psychiatry			
ONCOLOGY CLASSES AND SPECIALTIES			
Class = (AMI - AROMITASE INHIBITORS) FEM - Femara AMX - Arimidex ARO - Aromasin			
Specialties - AMI Class PCP - Primary Care (FP, GP, IM) HEM - Hematology, Hematology Oncology (HEM, HO) ONC - Oncology A/O - All Other Specialties			
SENIOR CARE CLASSES AND SPECIALTIES			
Class = (OST - OSTEOPOROSIS) MIB - Miacalcin Nasal Spray FOS - Fosamax (All forms) EVI - Evista		Class = (ALZ - ALZHEIMER) EXL - Exelon ACP - Aricept RMN - Reminyl	
Specialties - OST Class PCP - Primary Care (FP, GP, IM) OBG - Obstetricians/Gynecologists RHU - Rheumatologists A/O - All Other Specialties		Specialties - ALZ Class PCP - Primary Care (FP, GP, IM) N - Neurology P - Psychiatry A/O - All Other Specialties	
PHYSICIAN SPECIALTIES			
All physician specialty codes are certified with IMS Board codes, and are consistent with the specialty codes that are used to calculate incentives.			
TARGETS			
All targets are based upon frozen targets for the lead sales force for each product. For example, Lamisil targets are based upon the Galgy Field Force.			
Please note that when looking at a breakdown of targets, there are different number of targets for each tier per geography. It may appear that a lower target tier contains more volume, but that lower tier may also contain many more physicians. Please refer to the Monthly QTC Report for target counts by tier.			
Mass Market, Cardiovascular, Resp/Skin Disease, Oncology			
Target Tiers 1 - Tier 1 2 - Tier 2 3 - Tier 3 N - Non Target			
Senior Care Target Tiers 1 - Tier 1 2 - Tier 2 3 - Tier 3			
NeuroScience Target Tiers 10 - Decile 10 (Highest Tier) 9 - Decile 9 8 - Decile 8 7 - Decile 7 6 - Decile 6 R - Field Added Target		5 - Decile 5 4 - Decile 4 3 - Decile 3 2 - Decile 2 1 - Decile 1 (Lowest Tier) N - Non Target	

Mass Market Analysis
4/12/2004

CENTRAL REGION SPEAKERS

The Speakers are listed by Product and Sales Area.

The Speakers Highlighted in are considered as National or Regional Level Speakers.

Speakers who may be better known or willing to travel more.

Whenever you contact a Speaker Directly and have a confirmed date or event, please, notify the ASM or Specialist as a courtesy so they can be aware and in the know.

Contact A Specialist who calls on this Speaker and can be contacted for assistance.

Comments Provides some info on Speakers and or their Staff

Honorariums Should not be assumed to be exact or final. These are provided to give a general range. We should always seek to negotiate a good ROI.

MS_1619

CONTACT	PROST NAME	LAST	SPEC	WORKSHEET	PHONE	PAX	ADDRESS	CITY	STATE	ZIP	COMMENTS
ACT14	Bush	Mark	Peak	Heaven	1000 399-565-8204	501-325-0001	3300 S. Chippewa Park	Neenah	WI	53551	
	Koronen	Arvid	Peak	Peak	1000 391-837-2171	51-495-5001	5301 N. Federal Highway	Neenah	WI	53552	
	Zent	Bruce	Neuro	Neuro	1000 391-837-1778	84-341-1545	1360 HWY 94 S. Suite 9	Neenah	WI	53512	Very technical - widely respected
	de Toledo	John	Neuro	Neuro	300-243-5944	335-243-0288	1100 N.W. 8, S. 8-113	Neenah	WI	53512	Very well respected - American residents in Jackson Township above
	Steele	David	Neuro	Neuro	305-336-3595	335-203-3550	21150 Mendota Blvd. S.203	Appleton	WI	54910	
ACT15	WILLIAMS	TATIANA	N	750-1000	013-871-0811	013-871-0821	1301 WINDY CREEK BLVD. CH	TAMPA	FL	33613	MPHC
	JOSE	FERRERA	PELIN	750-1000	013-873-5028	013-873-5028	2901 W. ST. TAMARA, STE. D	TAMPA	FL	33607	MPHC
	ARCHER	GUILLERMO	PELIN	750-1000	013-873-2816	013-873-2827	5125 N. FORT MEADE AVE.	TAMPA	FL	33605	MPHC
	Thomas	Thomas	N	750-1000	013-873-2816	013-873-2816	4020 N. FORT MEADE AVE. J-1	TAMPA	FL	33605	MPHC
	BELOU	RENEE	N	750-1000	013-873-2816	013-873-2816	707-485-7153	St. Petersburg	FL	33001	Worked with Dr. Beggs
ACT16	Stephen	Escobedo	HU	31-500	335-309-3781	335-332-0893	7074 DAVIS ST., PO BOX 1269	Granada	FI	33031	Best presentation skills but not a strong CV
	Paul	Conroy	HU	31-500	335-309-3781	335-332-0893	2003 W. 10th Ave. Unit H	Granada	FI	33031	
	BERN	WOLTERS	HU	31-500	335-309-3781	335-332-0893	4003 W. 10th Ave. Unit H	Granada	FI	33031	
	DEANE	COCHRANE	HU	31-500	335-309-3781	335-332-0893	1702 WEST ST. SUITE 700	Granada	FI	33031	
	R. Elmir	Farrington	HU	31-500	335-309-3781	335-332-0893	1702 WEST ST. SUITE 700	Granada	FI	33031	
ACT17	Spina	11448	Spina	11448	205-914-2566	102-914-2566	1715 South Ave. South	Albany	AL	35007	Very AL - Strong CV - Good speaker
	JOHN	MATHESON	PELIN	31-500	335-309-3781	335-332-0893	1715 South Ave. South	Albany	AL	35007	
	COOK	41391	COOK	41391	335-309-3781	335-332-0893	1715 South Ave. South	Albany	AL	35007	
	COOK	41391	COOK	41391	335-309-3781	335-332-0893	1715 South Ave. South	Albany	AL	35007	
	COOK	41391	COOK	41391	335-309-3781	335-332-0893	1715 South Ave. South	Albany	AL	35007	
ACT18	LENN	14500	LENN	14500	0809-545-3322	0809-545-3322	707 Mendota Road	Granada	FI	33031	
	LENN	14500	LENN	14500	0809-545-3322	0809-545-3322	707 Mendota Road	Granada	FI	33031	
	LENN	14500	LENN	14500	0809-545-3322	0809-545-3322	707 Mendota Road	Granada	FI	33031	
	LENN	14500	LENN	14500	0809-545-3322	0809-545-3322	707 Mendota Road	Granada	FI	33031	
	LENN	14500	LENN	14500	0809-545-3322	0809-545-3322	707 Mendota Road	Granada	FI	33031	
ACT19	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon
	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon
	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon
	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon
	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon	19355	Ken	Sheldon
ACT20	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE
	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE
	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE
	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE
	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE	19355	DIANE

Trileptal National Medicaid Reimbursement 2000-2003

State	Labeler Code	Product Code	Package Size	Year	QTR	Product Name	Total Units Reimbursed	Total Prescriptions	Total Amount Reimbursed	Primary Key
XX	78	336	5	2000	1	TRILEPTAL	22,016.00	258	\$18,076.83	1835344578
XX	78	336	5	2000	2	TRILEPTAL	139,615.00	1587	\$112,413.23	1835344579
XX	78	336	5	2000	3	TRILEPTAL	284,089.00	3294	\$225,176.09	1835344580
XX	78	336	5	2000	4	TRILEPTAL	489,549.00	5884	\$391,591.13	1835344581
XX	78	336	6	2000	3	TRILEPTAL	605.00	3	\$498.72	1835344582
XX	78	336	6	2000	4	TRILEPTAL	4,627.00	51	\$4,242.72	1835344583
XX	78	337	5	2000	1	TRILEPTAL	85,134.00	913	\$126,177.14	1835344584
XX	78	337	5	2000	2	TRILEPTAL	650,898.00	6446	\$955,105.28	1835344585
XX	78	337	5	2000	3	TRILEPTAL	989,611.50	9981	\$1,447,875.41	1835344586
XX	78	337	5	2000	4	TRILEPTAL	1,511,105.00	16512	\$2,208,679.99	1835344587
XX	78	337	6	2000	3	TRILEPTAL	100.00	1	\$150.98	1835344588
XX	78	337	6	2000	4	TRILEPTAL	4,663.00	57	\$6,918.55	1835344589
XX	78	338	5	2000	1	TRILEPTAL	26,379.00	298	\$70,742.17	1835344590
XX	78	338	5	2000	2	TRILEPTAL	197,125.00	2336	\$529,903.18	1835344591
XX	78	338	5	2000	3	TRILEPTAL	301,826.00	3613	\$807,133.47	1835344592
XX	78	338	5	2000	4	TRILEPTAL	449,309.00	5700	\$1,188,140.07	1835344593
XX	78	338	6	2000	3	TRILEPTAL	60.00	1	\$167.72	1835344594
XX	78	338	6	2000	4	TRILEPTAL	2,066.00	35	\$5,783.78	1835344595
XX	78	336	5	2001	1	TRILEPTAL	645,269.00	7991	\$523,425.89	1835344596
XX	78	336	5	2001	2	TRILEPTAL	925,221.00	11955	\$774,774.55	1835344597
XX	78	336	5	2001	3	TRILEPTAL	1,239,674.00	16148	\$1,041,359.40	1835344598
XX	78	336	5	2001	4	TRILEPTAL	1,589,788.00	21165	\$1,337,896.60	1835344599
XX	78	336	6	2001	1	TRILEPTAL	6,318.00	88	\$5,568.38	1835344600
XX	78	336	6	2001	2	TRILEPTAL	12,518.00	172	\$11,177.62	1835344601
XX	78	336	6	2001	3	TRILEPTAL	22,646.00	319	\$19,104.63	1835344602
XX	78	336	6	2001	4	TRILEPTAL	27,363.00	401	\$24,013.63	1835344603
XX	78	337	5	2001	1	TRILEPTAL	1,923,740.10	21585	\$2,813,172.90	1835344604
XX	78	337	5	2001	2	TRILEPTAL	2,544,461.05	29349	\$3,826,915.75	1835344605
XX	78	337	5	2001	3	TRILEPTAL	3,388,997.64	39189	\$5,085,581.58	1835344606
XX	78	337	5	2001	4	TRILEPTAL	4,201,060.00	49164	\$6,272,876.75	1835344607
XX	78	337	6	2001	1	TRILEPTAL	10,517.00	130	\$16,356.33	1835344608
XX	78	337	6	2001	2	TRILEPTAL	23,538.00	271	\$38,617.23	1835344609
XX	78	337	6	2001	3	TRILEPTAL	25,697.00	300	\$42,099.05	1835344610
XX	78	337	6	2001	4	TRILEPTAL	34,237.00	434	\$55,755.09	1835344611
State	Labeler Code	Product Code	Package Size	Year	QTR	Product Name	Total Units Reimbursed	Total Prescriptions	Total Amount Reimbursed	Primary Key

Trileptal National Medicaid Reimbursement 2000-2003

State	Labeler Code	Product Code	Package Size	Year	QIR	Product Name	Total Units Reimbursed	Total Prescriptions	Total Amount Reimbursed	Primary Key
XX	78	338	5	2001	1	TRILEPTAL	633,470.00	8378	\$1,685,587.25	1835344612
XX	78	338	5	2001	2	TRILEPTAL	850,283.35	11376	\$2,323,210.19	1835344613
XX	78	338	5	2001	3	TRILEPTAL	956,821.00	13009	\$2,616,678.74	1835344614
XX	78	338	5	2001	4	TRILEPTAL	1,171,961.00	16248	\$3,207,568.84	1835344615
XX	78	338	6	2001	1	TRILEPTAL	6,890.00	142	\$19,472.68	1835344616
XX	78	338	6	2001	2	TRILEPTAL	9,548.00	301	\$28,072.28	1835344617
XX	78	338	6	2001	3	TRILEPTAL	11,093.00	229	\$32,910.81	1835344618
XX	78	338	6	2001	4	TRILEPTAL	18,634.00	201	\$38,160.51	1835344619
XX	78	357	52	2001	3	TRILEPTAL	137,116.00	519	\$42,963.40	1835344620
XX	78	357	52	2001	4	TRILEPTAL	477,319.24	1800	\$150,106.65	1835344621
XX	78	336	5	2002	1	TRILEPTAL	1,850,624.50	25045	\$1,612,389.68	1835344622
XX	78	336	5	2002	2	TRILEPTAL	2,363,103.00	32716	\$2,124,568.73	1835344623
XX	78	336	5	2002	3	TRILEPTAL	2,841,717.00	39537	\$2,567,829.61	1835344624
XX	78	336	5	2002	4	TRILEPTAL	3,207,191.00	44637	\$2,867,747.29	1835344625
XX	78	336	6	2002	1	TRILEPTAL	37,942.00	597	\$36,404.81	1835344626
XX	78	336	6	2002	2	TRILEPTAL	50,719.00	808	\$49,320.74	1835344627
XX	78	336	6	2002	3	TRILEPTAL	68,796.00	1052	\$65,564.06	1835344628
XX	78	336	6	2002	4	TRILEPTAL	74,882.00	1183	\$71,212.13	1835344629
XX	78	337	5	2002	1	TRILEPTAL	4,792,222.00	56938	\$7,463,646.36	1835344630
XX	78	337	5	2002	2	TRILEPTAL	5,996,792.02	73222	\$9,608,977.52	1835344631
XX	78	337	5	2002	3	TRILEPTAL	7,065,215.19	87331	\$11,359,419.26	1835344632
XX	78	337	5	2002	4	TRILEPTAL	7,929,144.00	97875	\$12,562,702.93	1835344633
XX	78	337	6	2002	1	TRILEPTAL	45,161.00	524	\$70,688.92	1835344634
XX	78	337	6	2002	2	TRILEPTAL	45,630.00	606	\$76,979.75	1835344635
XX	78	337	5	2002	3	TRILEPTAL	57,914.00	770	\$96,806.20	1835344636
XX	78	337	6	2002	4	TRILEPTAL	80,175.00	1064	\$133,781.18	1835344637
XX	78	338	5	2002	1	TRILEPTAL	1,335,976.85	18791	\$3,787,972.09	1835344638
XX	78	338	5	2002	2	TRILEPTAL	1,683,806.00	24165	\$4,925,989.41	1835344639
XX	78	338	5	2002	3	TRILEPTAL	1,996,980.50	28948	\$5,829,540.70	1835344640
XX	78	338	5	2002	4	TRILEPTAL	2,274,021.00	33433	\$6,618,159.25	1835344641
XX	78	338	6	2002	1	TRILEPTAL	49,798.00	220	\$43,983.73	1835344642
XX	78	338	6	2002	2	TRILEPTAL	41,479.00	299	\$56,523.51	1835344643
XX	78	338	6	2002	3	TRILEPTAL	24,329.00	289	\$57,351.16	1835344644
XX	78	338	6	2002	4	TRILEPTAL	29,064.00	456	\$90,246.69	1835344645
XX	78	357	52	2002	1	TRILEPTAL	810,851.00	3024	\$251,952.95	1835344646
XX	78	357	52	2002	2	TRILEPTAL	1,247,248.60	4500	\$384,480.92	1835344647

Trileptal National Medicaid Reimbursement 2000-2003

XX	78	357	52	2002 3	TRILEPTAL	1,881,376.56	6295	\$542,578.22	1835344648
XX	78	357	52	2002 4	TRILEPTAL	2,240,533.46	7902	\$676,563.15	1835344649
XX	78	336	5	2003 1	TRILEPTAL	3,489,244.59	47391	\$3,183,961.69	1835344650
XX	78	336	5	2003 2	TRILEPTAL	3,995,268.10	56836	\$3,774,775.55	1835344651
XX	78	336	5	2003 3	TRILEPTAL	4,275,941.50	59969	\$4,026,396.67	1835344652
XX	78	336	5	2003 4	TRILEPTAL	2,515,863.40	35810	\$2,359,347.35	1835344653
XX	78	336	6	2003 1	TRILEPTAL	82,031.00	1254	\$81,296.88	1835344654
XX	78	336	6	2003 2	TRILEPTAL	78,517.00	1170	\$77,103.50	1835344655
XX	78	336	6	2003 3	TRILEPTAL	94,127.00	1605	\$92,884.86	1835344656
XX	78	336	6	2003 4	TRILEPTAL	51,271.50	801	\$53,136.76	1835344657
XX	78	337	5	2003 1	TRILEPTAL	8,458,933.45	105130	\$14,080,663.07	1835344658
XX	78	337	5	2003 2	TRILEPTAL	9,841,571.00	123367	\$16,608,884.62	1835344659
XX	78	337	5	2003 3	TRILEPTAL	10,862,255.51	135964	\$18,353,438.77	1835344660
XX	78	337	5	2003 4	TRILEPTAL	5,927,239.40	75028	\$9,930,149.03	1835344661
XX	78	337	6	2003 1	TRILEPTAL	80,943.00	1075	\$144,361.96	1835344662
XX	78	337	6	2003 2	TRILEPTAL	95,458.00	1311	\$170,947.74	1835344663
XX	78	337	6	2003 3	TRILEPTAL	112,509.00	1815	\$200,096.43	1835344664
XX	78	337	6	2003 4	TRILEPTAL	70,844.00	1011	\$129,934.11	1835344665
XX	78	338	5	2003 1	TRILEPTAL	2,437,879.94	36074	\$7,357,142.60	1835344666
XX	78	338	5	2003 2	TRILEPTAL	2,869,194.50	42495	\$8,841,622.33	1835344667
XX	78	338	5	2003 3	TRILEPTAL	3,674,092.00	54366	\$11,346,566.28	1835344668
XX	78	338	5	2003 4	TRILEPTAL	2,019,974.20	30232	\$6,171,136.87	1835344669
XX	78	338	6	2003 1	TRILEPTAL	27,046.00	429	\$86,323.21	1835344670
XX	78	338	6	2003 2	TRILEPTAL	33,017.00	542	\$106,896.02	1835344671
XX	78	338	6	2003 3	TRILEPTAL	51,481.00	1100	\$167,174.76	1835344672
XX	78	338	6	2003 4	TRILEPTAL	28,048.00	454	\$92,091.27	1835344673
XX	78	357	52	2003 1	TRILEPTAL	2,567,710.00	8980	\$829,333.31	1835344674
XX	78	357	52	2003 2	TRILEPTAL	3,225,020.00	11222	\$1,088,110.95	1835344675
XX	78	357	52	2003 3	TRILEPTAL	3,984,341.60	13586	\$1,330,709.81	1835344676
XX	78	357	52	2003 4	TRILEPTAL	2,165,322.50	7156	\$699,743.93	1835344677

Cumulative Totals 2000-2003		
Units Reimbursed	Prescriptions	Amount Reimbursed
149,290,993.75	1,755,711.00	\$225,548,983.47

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, and the)
States of ILLINOIS, CALIFORNIA,)
FLORIDA, TEXAS, TENNESSEE,)
DELAWARE, NEVADA, LOUISIANA,)
HAWAII, INDIANA, NEW HAMPSHIRE,)
MICHIGAN, MONTANA, NEW MEXICO,)
NEW YORK, GEORGIA, RHODE ISLAND,)
OKLAHOMA, NEW JERSEY, WISCONSIN,)
CONNECTICUT, NORTH CAROLINA,)
the Commonwealths of)
MASSACHUSETTS and VIRGINIA,)
and the DISTRICT OF COLUMBIA,)
ex rel Steve M. McKee,)

No. 04-CV-1664

FILED UNDER SEAL PURSUANT
TO 31 U.S.C. § 3730(b)(2)

SECOND AMENDED COMPLAINT
FOR VIOLATIONS OF THE
FEDERAL FALSE CLAIMS
ACT AND VARIOUS STATE
FALSE CLAIMS ACTS

JURY TRIAL DEMANDED

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

Relator, Steve M. McKee, brings this action under the federal False Claims Act, as amended,
31 U.S.C. § 3729 *et. seq.*, as well as various state false claims statutes, and alleges as follows:

INTRODUCTION

1. This is a *qui tam* action brought by Steve M. McKee for himself and on behalf of the United States and various States to recover penalties and damages arising from defendant Novartis' fraudulent schemes to increase the market share of certain of its prescription drug products by means of: (1) an aggressive campaign to promote its anti-seizure drug, Trileptal for "off-label" uses in psychiatry, and particularly, the treatment of bipolar disorder, a serious, chronic mental illness; and

(2) its systematic payment of kickbacks to doctors across the country in the form of sham “consultant” and “speaking” arrangements to induce the doctors who receive these payments to favor Novartis’ products over that of its competitors. Novartis deliberately concealed its fraudulent schemes from the government-funded health care programs who pay for prescription drug coverage, and as a result, these programs unknowingly paid, and continue to pay, millions of dollars per year in connection with those schemes.

2. With respect to its off-label promotion campaign, Novartis flouted the FDA requirements and decided not even to seek FDA approval of Trileptal as a treatment for bipolar disorder but instead to aggressively market the drug for this use in the absence of the necessary safety and efficacy studies required by the FDA. As part of this strategy, Novartis concealed critical negative studies and data concerning Trileptal’s use in psychiatry and particularly, unflattering comparisons of the drug to lithium, the FDA-approved and undisputed “first-line” treatment for bipolar disorder. All of these actions were undertaken for the sole purpose of Novartis’ own financial gain, at the expense of government-funded health care programs and the patients who are reliant on those programs.

3. As a result of Novartis’ off-label promotion and kickback schemes, the company caused the submission of hundreds of thousands of false claims to government-funded health care programs across the country that pay for prescription drug coverage for their recipients. These schemes cost the Medicaid programs alone at least one-hundred million dollars during the time period of 2000 through 2003, and with respect to Trileptal only. This complaint, which details Novartis’ off-label promotion and kickback schemes, is based upon non-public information Relator obtained during the course of his thirteen years of employment by Novartis, and his personal observation of the acts and conduct described herein.

4. In connection with the filing of this Complaint, Relator also furnished the United States and state governments with the disclosure statement required by 31 U.S.C. § 3730(b)(2) and like provisions of the state false claims acts, including thousands of pages of documents evidencing and supporting the fraudulent schemes described herein. Relator is the original source of all of the facts and information contained in this complaint and voluntarily provided that information to the government prior to filing his complaint.

THE PARTIES

5. Relator, Steve M. McKee (“McKee”), is a citizen of the United States and a resident of the state of North Carolina. McKee was employed by Novartis (formerly Ciba-Geigy Pharmaceuticals) as a pharmaceutical sales representative from August 1990 until September 2003. Throughout his career with the company, McKee worked with a wide range of pharmaceutical products and disease states. McKee regularly received performance-based bonuses, raises and promotions.

6. In January 2002, McKee was promoted to the Neuroscience Specialty Division, with responsibility for the sale of prescription drug products Exelon, Comtan and Trileptal. McKee’s excellent employment record at Novartis changed only after he joined this new division, where he soon learned Novartis required the sales representatives in that division to promote off-label uses of Trileptal to psychiatrists and other physicians. McKee voiced concerns over the off-label promotion requirements to his supervisor and senior sales representatives in his region throughout the summer of 2002. In response, McKee was told simply that he would “get used to it” and that targeting psychiatrists was the fastest way to gain market share.

7. In mid-2002 and because of the off-label promotion requirements, McKee requested a transfer out of the neuroscience division. McKee’s transfer was denied due to a company policy

requiring a sales representative to remain in a division for at least two years before seeking a transfer. McKee remained in the division and in the fall of 2002, he again told his supervisor he was uncomfortable with promoting Trileptal off-label to psychiatrists, that there was no real data to support the use of the drug in psychiatry. McKee advised his supervisor he refused to initiate any off-label sales discussions with psychiatrists or otherwise promote the product off-label as required by the company. By June 2003, McKee was placed on a Performance Improvement Plan and in September 2003, was terminated for allegedly failing to make his sales goals.

8. Novartis Pharmaceuticals Corporation (hereinafter “Novartis” or “the company”) is a division of Novartis AG, a global pharmaceutical company created in 1996 from the merger of Swiss companies, CIBA-Geigy AG and Sandoz AG. In 2003, Novartis AG achieved sales of nearly \$30 billion and a net income of \$5 billion. Novartis AG is headquartered in Basel, Switzerland, operates in over 140 countries around the world and employs about 78,500 people.

9. According to its internet website, Novartis is a “world leader in the discovery, development, manufacture and marketing of prescription medicine.” *See* www.novartis.com. Headquartered in East Hanover, New Jersey, Novartis consists of five business units: primary care, oncology, transplantation, ophthalmics and mature products. Of relevance here, the primary care unit includes products to treat central nervous system disorders such as schizophrenia, epilepsy, Parkinson’s disease, Alzheimer’s disease, attention deficit hyperactivity disorder and migraine headaches. Within the primary care unit, the key products of the neuroscience division include Comtan, Exelon, Focalin, Clozaril/Leponex, Ritalin, Tegretol, and Trileptal.

JURISDICTION AND VENUE

10. This is a civil action arising under the laws of the United States, and specifically, 31 U.S.C. § 3730, the “False Claims Act.” Therefore, this Court has jurisdiction over this action pursuant to 31 U.S.C. § 3732 (a) and (b).

11. Venue is proper in this district pursuant to 31 U.S.C. § 3732 (a) because Defendant Novartis transacts substantial business in this district and also maintains permanent employees and corporate offices in this district. Defendant also committed numerous acts proscribed by 31 U.S.C. § 3729 in this district..

12. This Court has supplemental jurisdiction over the state law claims contained in this action pursuant to 28 U.S.C. § 1367(a), as such claims form part of the same case or controversy as the federal claims.

FACTUAL BACKGROUND

THE REGULATION OF PRESCRIPTION DRUG SALES AND MARKETING ACTIVITIES IN THE UNITED STATES

13. The Food, Drug and Cosmetic Act (FDCA or the Act) governs the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce. Under the FDCA, new drugs cannot be distributed in interstate commerce unless and until the manufacturer demonstrates to the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355 (a) and (d). While pursuant to the “medical practice exception,” an individual physician may prescribe a drug for a use other than one for which it is approved, the FDA prohibits a drug manufacturer from marketing or promoting a drug for non-approved uses. 21 U.S.C. § 331(d) and § 355(a). Likewise, a drug manufacturer’s sales representatives are prohibited from initiating discussions with physicians regarding any off-label uses

of a drug. The dissemination of information or materials by a pharmaceutical manufacturer on any unapproved or off-label uses constitutes unlawful promotional advertising or “misbranding” of the drug and violates the FDCA (this activity is referred to as “off label” marketing or promotion).

14. A limited exception to the prohibition on off-label promotion (not applicable here) is provided for in the FDA Modernization Act of 1997. The limited exception comes into play where a pharmaceutical manufacturer has committed to seeking FDA approval for the new use and has notified the FDA of its intent. 21 U.S.C. § 355 (codified at Pub. L. No. 105-115). Even in that circumstance, the manufacturer must comply with strict requirements, including that it must submit any off-label use materials it plans to disseminate to physicians to the FDA for pre-approval.

15. The reason for the prohibition on off-label promotion by drug manufacturers is many-fold: (1) this activity diminishes or eliminates the drug manufacturer’s incentive to study the use and obtain definitive safety and efficacy data; (2) off-label promotion could result in harm to patients from unstudied uses that actually lead to bad results, or that are merely ineffective; (3) it diminishes the use of evidence-based medicine; and (4) could ultimately erode the efficacy standard in medicine. *See* Presentation by Janet Woodcock, MD (Director of the FDA’s Center for Drug Evaluation and Research), June 23, 1997 available at www.fda.gov/cder/present/diamontreal/regappr/sld001.htm.

THE ANTI-KICKBACK ACT’S PROHIBITIONS

16. Under the federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), it is illegal to knowingly and willfully offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) that is payable in whole or in part by any federally-funded health care programs, including Medicare and Medicaid. These federal health care programs require that providers seeking payment by these programs certify compliance with the

provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in America.

17. The Anti-Kickback Act prohibits pharmaceutical manufacturers from making any payments, in cash or in kind, to any health care provider where a purpose of such payment is to influence the provider's prescribing habits or, to put it another way, to gain favor for its product over that of a competitor. Activities that have come under attack under this statute include payments by pharmaceutical manufacturers to physicians for sham "consulting" services, illusory "training" sessions, bogus research and "educational" grants, lavish meals, entertainment and other gifts and discounts. These activities are particularly suspect where a drug manufacturer selects physicians for these payments, based not on their professional resume or services actually provided to the company, but rather, on their ability or potential to prescribe the company's products. The Anti-Kickback Act's prohibitions are designed to ensure patient care will not be improperly influenced by the deep pockets of the pharmaceutical industry.

**THE REIMBURSEMENT CRITERIA USED BY
GOVERNMENT-FUNDED HEALTH CARE PROGRAMS**

18. The federal and state governments pay for prescription drug benefits under a variety of health care programs. The most well known of these programs is Medicaid, which provides health care coverage, including prescription drug benefits, for the poor and disabled. The Medicaid program, administered by the Center for Medicare and Medicaid Services (CMS), is jointly funded by the federal and state governments. Other government-funded health care programs that pay for prescription drug coverage for their members or recipients include CHAMPUS/Tricare, the Veteran's Health Administration and Federal Employees' Health Benefits Program (FEHB), among others (all of these programs, including Medicaid are collectively referred to herein as the

“government-funded health care programs”).

19. While each of the government-funded health care programs varies slightly in its reimbursement criteria, none of these programs pay for medications that are not FDA approved or that are not for “medically accepted indications” (a “medically accepted indication” is a use that is supported by the medical compendia set forth in § 1396r-8(g)(1)(B)(i) of the FDCA). Bipolar disorder is not a “medically accepted indication” for Trileptal and therefore is not eligible for reimbursement for this use. Likewise, the government-funded health care programs do not pay for prescriptions resulting from false or misleading information disseminated by a pharmaceutical manufacturer or connected to illegal kickbacks paid by a pharmaceutical manufacturer.

NOVARTIS’ FRAUDULENT OFF-LABEL PROMOTION SCHEME

20. In January 2000, Novartis announced that its prescription drug product Trileptal (clinically known as oxcarbazepine) had received FDA approval for use in the treatment of epilepsy. Specifically, the FDA approved Trileptal for the treatment of partial seizures as mono or single drug therapy in adults or adjunctive therapy in adults and children ages four and up. In August, 2003, the FDA also approved Trileptal for use as a mono therapy in children with epilepsy. To date, Trileptal has not received FDA approval for any other use.

21. Nevertheless, almost immediately after launching Trileptal in February 2000, Novartis began an aggressive marketing scheme to promote uses of Trileptal other than the limited use approved by the FDA. Novartis, with very little in the way of medical or scientific data to support that Trileptal was safe and effective for any use other than in the treatment of epileptic seizures (and actually holding information to the contrary), and without the necessary safety trials being completed or even contemplated by the company, began touting Trileptal as a safe and effective treatment for bipolar disorder, a serious, chronic mental illness. Recent data suggests bipolar symptoms may

affect nearly eight million American adults, or one in thirty people. In contrast, the market for epilepsy is only a fraction of that (the condition affects approximately two million Americans). Among psychiatric illnesses, bipolar disorder carries one of the highest rates of suicide completion (as high as 10-15%) and up to 40% of patients with bipolar disorder also have problems with alcohol and drug use during their illness. Many patients with bipolar disorder require institutionalization at some point in their lives. There is presently no cure for the disease.

22. Novartis targeted psychiatrists in its promotion of Trileptal who, as a group, have no reason to prescribe the drug other than for off-label uses. Neurologists, on the other hand, are the most common prescribers of FDA-approved uses of Trileptal. In setting up the off-label promotion scheme, Novartis devoted sales representatives in three of its four neuroscience divisions to the task and required them to promote Trileptal to the psychiatrists on the “target” lists it generated and distributed to its sales force. *See* representative Novartis Target lists for 2002 and 2003, attached as Exh. A. Since psychiatrists do not prescribe Trileptal for any FDA-approved indications, the only discussions that could possibly take place on these sales calls were off-label discussions. Failure of the Novartis sales representatives to make the off-label sales calls to psychiatrists led to negative employment reviews and discipline and negatively impacted any potential merit pay increases they might otherwise receive.

23. To further encourage the off-label promotion activities of its sales force, Novartis paid bonuses for upward shifts in Trileptal market share generated by psychiatrists. The bonus plan continued through 2000, 2001, 2002 and mid-way through 2003. Novartis sales representatives were instructed that psychiatrists were “low hanging fruit” and easy targets for the off-label promotion activities and bonus opportunity.

24. Also beginning as early as the first quarter of 2000, Novartis dedicated a distinct

marketing or promotional budget for the off-label use of Trileptal. According to records kept by the company and distributed to newly hired sales representatives during their training, by early 2001, Novartis was pouring \$250,000 - \$500,000 per month into the off-label promotion scheme. *See* Exh. B (Excerpt from Novartis' 2002 Neuroscience Division New Hire Training Manual).

**THE FALSE AND MISLEADING INFORMATION NOVARTIS PROVIDES TO PSYCHIATRISTS
AND ITS INITIATION OF OFF-LABEL USE DISCUSSIONS**

25. While off-label promotion under these circumstances is, in and of itself, strictly illegal, Novartis also began disseminating false and misleading information to the psychiatrists it targeted. As a general matter, information concerning safety and efficacy contained in Novartis' general promotional materials for Trileptal, when given to doctors in the field of psychiatry, are false and misleading in that none of the required safety and efficacy tests have been done (or here, even planned) for these patients and disease states. Nonetheless, Novartis sales representatives were told to leave these promotional materials, along with samples of the product on all of their sales calls to psychiatrists. None of these items contained any warning or notice that the FDA had not approved Trileptal for psychiatric indications.

26. Novartis also instructed its sales representatives to carry "Medical Request Forms" on their sales calls to psychiatrists and use them to "prompt" the psychiatrists to "ask" for information on Trileptal's off-label uses. While a physician is free to inquire about off-label uses of a drug, a sales representative may not initiate that communication or use a Medical Request Form for such a purpose (an example of a Medical Request Form is attached as Exh. C). In many cases, the Novartis sales representative even filled out the Medical Request Form in advance of the sales call. They then explained to the psychiatrist that in response to the doctor's "request," the company would provide him or her with all the medical data and studies regarding the off-label use.

27. As it turns out, decision-makers at Novartis' corporate headquarters decided to select out certain positive information in response to the purported requests (consisting mostly of "chart reviews" and single patient or small group studies) and to conceal the negative data and studies suggesting Trileptal is neither safe, nor effective in the treatment of bipolar disorder. The critical studies and data Novartis conceals from psychiatrists includes, but is not limited to:

- A three-year randomized study (Wildebrube 1990) comparing oxcarbazepine to lithium, the generic and "first line" FDA-approved treatment for bipolar disorder and other psychiatric conditions. This study showed "no clear responders" in the group treated with Trileptal.
- A double-blind multi-center trial (Grant & Faulds, 1992) comparing oxcarbazepine to lithium in acutely manic patients where the oxcarbazepine group displayed slower onset and a higher incidence of side effects.

28. Critically, these two studies compare Trileptal (oxcarbazepine) to lithium, the "first-line," *and* FDA- approved treatment for bipolar disorder. Lithium also is, and has been, available in generic form for well over a decade now. The studies concealed by Novartis conclude Trileptal *doesn't even work* for the treatment of bipolar disorder and in the case of the Grant & Faulds study, that Trileptal is *less effective* than Lithium and *less safe* for patients. All of this wholly unflattering information would be material to any doctor's decision-making and is nonetheless absent in the thousands of Medical Information Requests Novartis distributes to psychiatrists across the country in response to their purported "requests" for information. As only one example, Novartis failed to disclose this negative information in materials distributed by Novartis' Medical Information Specialist to Dr. Rigardy Munoz on February 25, 2003 (attached as Exh. D). This information is also not disclosed during any of the off-label sales calls Novartis requires its sales representative to make.

29. The names of additional psychiatrists whom Novartis disseminated false information

as described herein are contained in the “target lists” attached as Exh. A. Novartis sales representatives disseminated the false and misleading information during sales calls to these and other psychiatrists from February 2000 through at least September 2003 when Relator left the company, and likely beyond. A complete listing of psychiatrists who received false and misleading information from Novartis concerning the off-label use of Trileptal in the treatment of bipolar disorder, including each exact date upon which such misrepresentations were made lies solely in the possession of defendant Novartis and is easily obtainable by review of its own records. These records consists of all of the Medical Information Request letters described above and the records of each and every sales call a Novartis sales representatives made to a psychiatrist for Trileptal, which were recorded by the sales representatives and tracked and maintained by the company (except for the calls Novartis instructed its sales force to deliberately keep out of its computer records after January 2003, as further described in paragraph 36 below).

30. Another common ploy Novartis employed in furtherance of its off-label promotion scheme was to illegally use CME materials in its sales activities. CME courses that include off-label use discussion are appropriate (and even valuable) so long as they are independent of a pharmaceutical manufacturer’s influence and are not provided in connection with sales and marketing activity. Nevertheless, Novartis sales representatives systematically distributed CME tapes and other materials involving bipolar disorder during their sales calls to psychiatrists, sometimes sitting through the presentation with the doctor in his or her office and even “queuing” the tape to the segment on Trileptal. These CME materials were sometimes shipped in bulk to Novartis sales representatives.

31. To date, no clinical studies of any validity or magnitude have been performed that demonstrate Trileptal is a safe and effective treatment for bipolar disorder. While a recent summary

known as the “Texas Algorithm” (first published in mid-2002 and already years into the off-label promotion scheme) suggests Trileptal as an alternate choice in the treatment of certain types of bipolar disorder where “first line” treatment does not work, and as a combination therapy, Novartis itself declined to expend its resources to conduct any clinical studies or research to support this use of the drug or even to ensure its safety in patients suffering from the disorder. When the Texas Algorithm became available, Novartis sales representatives began distributing it to psychiatrists on their sales calls but continued to conceal the negative information also failed to inform psychiatrists the company was not going to even seek FDA approval for Trileptal’s use in psychiatry.

32. As another element of its effort to illegally tout the benefits of off-label uses of Trileptal while concealing the negative data, Novartis downplays the potential side effects of the drug, and in particular, the serious risk of hyponatremia. Left untreated, hyponatremia may cause sodium levels to drop to the point of coma or even death. Novartis claims the incidence of hyponatremia for Trileptal patients is 2.5%, already a clinically significant number, but bases its claim on outdated, European studies. Individual physicians have experienced hyponatremia rates in their patients as high as 25-40%. The risk of hyponatremia (or any other of Trileptal’s known side effects) may be of even greater concern to psychiatric patients who are taking more than one medication or who have alcohol or drug-related problems (both common in patients with bipolar disorder). Since the necessary patient safety testing has not been done in the context of psychiatry, the real risk to these vulnerable patients remains unknown. As researchers at Novartis’ Basel, Switzerland headquarters report:

CBZ [carbamazepine] has led to hyponatremia in patients with epilepsy, neuralgia, mental retardation, and psychiatric disorders with a frequency varying from 4.8 to 40%. Oxcarbazepine (OCBZ), which is structurally related to CBZ, has shown similar hyponatremic effects, but whether hyponatremia occurs more often than with CBZ

is not yet clear. Experience with OCBZ is still limited, and there is no definite explanation for a possible difference in antidiuretic potency.

Van Amelsvoort, Devaus and Schwabe (1994). Thus, according to Novartis' own researchers, the risk of hyponatremia is potentially as great as 40% or higher. The serious and substantial risk of hyponatremia (coupled with the substantial expense involved in conducting the necessary efficacy and safety trials) was a key factor in Novartis' decision not to seek FDA approval for any psychiatric indications of Trileptal. Additional adverse events associated with the use of Trileptal include dizziness, somnolence (prolonged sleepiness), diplopia (double vision), fatigue, nausea, vomiting, ataxia (muscle coordination problems), abnormal vision, abdominal pain, tremor (involuntary quivering or convulsing), dyspepsia and abnormal gait.

NOVARTIS' DECISION TO FLOUT THE FDA REQUIREMENTS

33. Novartis instituted its fraudulent off-label promotion scheme even though it never intended to expend the resources to conduct patient safety and efficacy trials or to ever seek FDA approval for psychiatric indications and uses. At a January 2003 national meeting (already three years into the off-label promotion scheme), Novartis management formally announced to its sales force that it was not "economically viable" to conduct the necessary medical trials for psychiatric indications for Trileptal and therefore it would not be doing so. Rather, the company was going to wait and produce a new drug that would have fewer hyponatremia and other problems. The company's patent for Trileptal was set to expire in approximately 2008, just in time for this new drug to be launched, thereby effectuating a transition with no financial "downtime" for Novartis.

THE SUCCESS OF THE OFF-LABEL PROMOTION SCHEME

34. Novartis' off-label promotion scheme was so successful that as early as December 2001, psychiatrists nearly overtook neurologists in regard to Trileptal sales volume. *See* Exh. E

(Excerpt from PowerPoint presentation from Novartis' T2 2002 national sales meeting). As further illustration, at the end of 2000, the field of psychiatry accounted for only 14% of all Trileptal prescriptions, but less than a year later, by November 2001, this number had jumped to 38% and the proportion of prescriptions written for the approved use of epileptic seizure control plummeted from 71% to 42%. *See* Exh. B. Trileptal's market share for psychiatry now dominates over the approved-use market:

TRILEPTAL PRESCRIPTIONS (TRx) BY YEAR*

2001 - **42%** of TRx attributable to psychiatry

2002 - **56%** of TRx attributable to psychiatry

(1st trimester) 2003 - **62%** of TRx attributable to psychiatry

**Source: Novartis Customer Segment Trend Reports (Exh. F).*

35. With the substantial and ever increasing boost from psychiatry, Trileptal became the most successful anti-epileptic drug launch, beating out Neurontin, Lamictal, Topamax, among others. Novartis' forecasted net sales for Trileptal of \$575 million by the year 2006. *See* Exh. E.

NOVARTIS STARTS TO COVER ITS TRACKS

36. Around January 2003, Novartis decided it was time to start covering its tracks. As its first step, Novartis removed several thousand psychiatrists from its sales "target" database. The off-label nature of sales calls to these physicians would be the most obvious to government regulators and prosecutors should they ever learn of Novartis' scheme. While these physicians were removed from the target database, Novartis continued to instruct its sales force to call on them, just not to record the calls in their computer system.

37. In May 2003, Novartis took the additional step of removing all psychiatrists from the "bonus" universe for Trileptal. This action was also a distinction without a difference because

Novartis continued to require its sales force to call on psychiatrists for Trileptal, it just wasn't going to pay them extra for it. By this point however, sales to psychiatrists already accounted for greater than 62% of Trileptal's market share and sales representative would have to continue to make these sales calls or watch their sales numbers plummet.

**NOVARTIS' USE OF ILLEGAL PAYMENTS OR KICKBACKS
TO FURTHER BOOST ITS MARKET SHARE**

38. Novartis additionally made outright cash payments to physicians to induce them to prescribe Trileptal, as well as most of its other drug products. Under the guise of "consultant" services or speaker "training," Novartis hand-picked high prescribers to participate in (and receive payments for) what amounted to sales and marketing programs, known as "Advisory Boards," "Forums" or "Faculty Development Meetings." The bogus nature of all of these programs is evidenced by Novartis' tracking of the attendees prescribing habits before and after the programs and by virtue of the fact that at no time, were attendees actually required to provide any services, consulting, speaking, or otherwise, to the company.

THE SHAM CONSULTANT MEETINGS

39. Novartis recruited psychiatrists and other physicians to attend so-called consultant meetings or "Advisory Boards" for Trileptal, where attendees received cash payments to the tune of \$200-500 simply for showing up. Speakers (themselves typically high prescribers) were paid \$1,000-1,500. Attendees at these meetings were paid to enjoy a lavish dinner where they would sit and listen to Novartis promotional messages. Novartis picked up tab at all of these dinners. Typically, a paid Novartis speaker would also show up to tout the benefits of Trileptal. If the speaker did not do so, Novartis would gently prompt the discussion into off-label uses of the drug. After dinner and drinks, it was not uncommon for Novartis to send the attending doctors home with free

bottles of wine or other gifts. While the attendees signed a “consultant agreement” with Novartis, they were not required to perform any services for the company. Novartis did provide attendees with an optional “feedback” form that directly asked attendees if they would prescribe more Trileptal as a result of the program.

40. Among the doctors who received the illegal kickbacks in connection with Advisory Board programs for Trileptal include Dr. Adrian Griffin (psychiatrist in Mount Airy, NC), Michael McClure, MD (psychiatrist in High Point, NC), Sarah Bullard, PA (physician’s assistant to Dr. McClure in High Point, NC), Andy Farah, MD (psychiatrist in High Point, NC), Elizabeth Wright, MD (neurologist in Statesville, NC), Frank Crowell, MD (neurologist in Winston-Salem, NC), Edward Weaver, MD (psychiatrist in Winston-Salem, NC), and Stephen Kirley, MD (psychiatrist in Clemmons, NC). All of these doctors received illegal payments in 2002, and likely on additional occasions as well. A complete listing of the doctors across the country who received these illegal payments (including exact days on which the payments were made) is available from Advanced Health Media (AHM) in New Jersey, a third party administrator of the programs for Novartis. AHM also sends the honoraria checks to the Novartis sales representatives who distribute them to the doctors.

41. After completion of the Advisory Board programs, Novartis tracked the prescribing habits of the attendees to determine its “return on investment” and whether these programs were successful in getting physicians to change their prescribing habits. Such an activity would not have been necessary if the purpose of the meetings was legitimate. These illegal payments were made with respect to Trileptal from February 2000 through at least August 2002, and possibly beyond and were nation-wide in scope. Advisory Boards were, and are, conducted with respect to additional prescription drug products including Diovan. Advisory Boards were conducted from 1997 to at least

August 2002.

42. Similar to the Advisory Boards, Novartis also conducted “Clinical Forums” that involved \$750 per doctor pay-outs and the Novartis “Consultant Network.” As an additional perk to participate in Consultant Network, the doctors were offered “Sample Solutions,” whereby Novartis would pay for supplies and send out its sales force to organize the doctor’s sample closets.

BOGUS SPEAKER “TRAINING”

43. Novartis also recruited “high prescribers” for participation in its national speaker “training” program, referred to as “Faculty Development” meetings. For Trileptal, the attendees included psychiatrists and other doctors who, because of their specialty, would not have reason to prescribe the FDA-approved use of the drug. Novartis hand-picked the physicians for these programs, based not on their medical knowledge, reputation or skills, but rather, by review of their ability and tendency to prescribe Novartis products. Novartis sales representatives who recruited the attendees explained that these physicians were under no obligation to speak for the company. The purported training sessions took place at five star or other lavish resorts in Florida or other attractive locations, and included presentations by paid Novartis speakers and the company itself. Attendees of these programs received \$750 honoraria plus an all expense paid trip, including airfare, lodging, meals and entertainment.

44. Among the doctors who received the illegal kickbacks in connection with Faculty Development Meetings for Trileptal include: David Meyers, MD (neurologist in Winston-Salem, NC), Christine Dean, MD (neurologist in Winston-Salem, NC), Cormac O’Donovan (neurologist in Winston-Salem, NC), Cesar Santos, MD (neurologist in Winston-Salem, NC), James Parrott (neurologist in Hickory, NC), John Porter (neurologist in Winston-Salem, NC), Beverly Jones, MD (psychiatrist in Winston-Salem, NC), Joseph Miller, MD (neurologist in High-Point, NC). On

information and belief, the following psychiatrists were among the paid speakers for the Trileptal Faculty Development programs: Eugene Dagon (Tampa, FL), Reddy Pasem (Ocala, FL), F. Cleveland Kinney (Birmingham, AL), Gary Newsom (Northport, AL), John Taylor (Greenville, SC), Ramesh Giwala (Gastonia, NC), and Borja Benedicto (Portsmouth, OH). All of these speakers, as well as the additional names on the Novartis speaker list designated as a “psych” or “P” speciality, attached as Exh. G -- are psychiatrists in private practice that would only have reason to speak about Trileptal’s off-label uses. The above physicians received the illegal kickbacks in 2002-2003 and possibly other occasions as well. A complete listing of the doctors across the country who received these illegal payments (including exact days on which the payments were made) is available from AHM.

45. The Faculty Development Meetings are nation-wide in scope, and with respect to Trileptal, began in January 2000 and continue to this day. The Faculty Development Meetings were, and are, conducted with respect to additional prescription drug products including Diovan. The Faculty Development Meetings date back to at least 1997, were in existence when Relator left the company in September 2003 and on information and belief, continue to this day.

46. Additional gratuities provided by Novartis to its favored physicians include payments for CME programs and medical certification classes. On information and belief, Novartis also supplied “grants” to physicians and institutions for the purpose of influencing prescribing habits in favor of its products.

47. All of the above programs, including the Advisory Boards, Clinical Forums, Faculty Development Meetings, Consultant Network, Sample Solutions, CME programs and grants are thinly disguised means to effectuate payment to physicians for the purpose of influencing their prescribing habits, in violation of the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), and the various

state counterparts prohibiting payment of money or other value to induce a referral that will be paid by a government-funded health care program.

**HOW NOVARTIS' FRAUDULENT OFF-LABEL PROMOTION AND KICKBACK SCHEMES
HARM GOVERNMENT-FUNDED PROGRAMS AND PATIENTS**

48. Novartis' fraudulent schemes drain government-funded health care programs of millions of dollars each year. By virtue of its intentional and deliberate conduct, Novartis caused hundreds of thousands of false claims to be submitted to these government-funded health care programs by doctors and pharmacists across the country who received the false and misleading information provided by Novartis concerning the off-label uses of Trileptal and/or who were the recipients of the kickbacks paid by the company to induce the doctors to write prescriptions for Trileptal and its other drugs. The government-funded health care programs described herein would not have paid for Trileptal prescriptions if these programs knew the prescriptions were the direct result of Novartis' dissemination of false and misleading information concerning the drug's safety and effectiveness for psychiatric patients and/or outright cash payments to the doctors who wrote the prescriptions. Specifically, false claims were submitted for reimbursement to the government-funded health care programs in connection with claims for reimbursement for Trileptal submitted by all of the doctors and pharmacists described in paragraphs 25-29, above, including all doctors who received the false and misleading Medical Information Requests and who were, and are, listed on Novartis' "target lists." False claims were also submitted in connection with all of the doctors who received and continue to receive the illegal kickbacks, including those listed in paragraphs 40 and 44, above. But for Novartis' conduct, the false claims for Trileptal or its other products would not have been submitted for reimbursement to the government-funded health care programs, nor paid by any these programs.

49. Trileptal has no generic equivalent and comes with a price tag of approximately \$150 a month. Lithium, one of at least three FDA-approved treatments for bipolar disorder, and recommended as a “first line” treatment by the American Psychiatric Association, among others, has been generically available since the mid-1970s. Additional FDA-approved treatments for bipolar disorder now include GlaxoSmithKline’s drug Lamictal, and Zyprexa, manufactured by Eli Lilly & Co.

50. National Medicaid reimbursement data shows that since January 2000, the state and federal governments have paid for 1,755,711 total prescriptions for Trileptal, to the tune of over two hundred twenty-five million dollars (\$225,548,983.47). *See* Exh. H. Using the data in paragraph 34 above, at least half of this amount or greater than one hundred million dollars is attributable to off-label prescriptions in psychiatry.

51. Separate and apart from the huge price tag, patients are harmed in that it is unknown whether Trileptal is safe and effective for the serious and chronic mental illness they suffer from.

COUNT I **FALSE CLAIMS ACT**

52. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

53. This is a *qui tam* action brought by Steve M. McKee and the United States Government to recover treble damages and civil penalties under 31 U.S.C.A. § 3729(a) of the False Claims Act.

54. 31 U.S.C.A. § 3729(a) provides, in relevant part, liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

(3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

55. Novartis violated 31 U.S.C.A. § 3729(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the United States Government from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

56. The United States Government, by and through CMS, CHAMPUS/Tricare, the VA and FEHB, and possibly other federal agencies, and unaware of Novartis' fraudulent off-label promotion and kickback schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

57. Compliance with applicable Medicare and Medicaid, and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of the payment of claims submitted to the United States Government by health care providers and third party payors in connection with Novartis' fraudulent schemes.

58. Had the United States Government known Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by

health care providers and third party payors for the drug products, in connection with those schemes.

59. As a result of Novartis' violations of 31 U.S.C.A. § 3729(a), the United States Government has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

60. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 31 U.S.C.A § 3730(b) on behalf of himself and the United States Government.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the UNITED STATES GOVERNMENT:

- (1) Three times the amount of actual damages which the United States Government has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Novartis presented or caused to be presented to the United States Government;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to 31 U.S.C.A. § 3730(d) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT II
ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT

61. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

62. This is a *qui tam* action brought by Steve M. McKee and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

63. 740 ILCS 175/3(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

64. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

65. Novartis violated 305 ILCS 5/8A-3(b) from at least 1997 to the present by engaging in the fraudulent schemes described herein.

66. Novartis furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the

FDCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

67. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

68. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Novartis' fraudulent schemes.

69. Had the State of Illinois known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

70. As a result of Novartis' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

71. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois.

72. This Court is requested to accept pendant jurisdiction of this related state claim as it is

predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF ILLINOIS:

- (1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Illinois;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT III
CALIFORNIA FALSE CLAIMS ACT

73. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

74. This is a *qui tam* action brought by Steve M. McKee and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

75. Cal. Gov't Code § 12651(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;

(3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.

(8) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

76. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

77. Novartis violated Cal. Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code §14107.2 from at least 1997 to the present by engaging in the fraudulent schemes described herein.

78. Novartis furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code §14107.2 and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-

funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

79. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

80. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Novartis' fraudulent schemes.

81. Had the State of California known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

82. As a result of Novartis' violations of Cal. Gov't Code §12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

83. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

84. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF CALIFORNIA:

- (1) Three times the amount of actual damages which the State of California has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of up to \$10,000 for each false claim which Novartis presented or caused to be presented to the State of California;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT IV
FLORIDA FALSE CLAIMS ACT

85. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

86. This is a *qui tam* action brought by Steve M. McKee and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

87. Fla. Stat. § 68.082(2) provides liability for any person who-
- (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or

approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;

(c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

88. In addition, Fla. Stat. § 409.920 makes it a crime to:

(c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;

* * * * *

(e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

89. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a health care provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

90. Novartis violated Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) from at least 1997 to the present by engaging in the fraudulent schemes described herein.

91. Novartis furthermore violated Fla. Stat. § 68.082(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Florida from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including

the FDCA, federal Anti-Kickback Act, Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

92. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

93. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Novartis' fraudulent schemes.

94. Had the State of Florida known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

95. As a result of Novartis' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

96. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

97. This Court is requested to accept pendant jurisdiction of this related state claim as it is

predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF FLORIDA:

- (1) Three times the amount of actual damages which the State of Florida has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Florida;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT V
TEXAS FALSE CLAIMS ACT

98. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

99. This is a *qui tam* action brought by Steve M. McKee and the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

100. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who-

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:

- (a) on an application for a contract, benefit, or payment under the Medicaid program; or
- (b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.

(2) knowingly or intentionally concealing or failing to disclose an event:

(a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:

- (i) the person; or
- (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and

(b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

(b) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(5) knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

101. Novartis violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and § 36.002, and by virtue of the fact that none

of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

102. The State of Texas, by and through the Texas Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

103. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Novartis' fraudulent schemes.

104. Had the State of Texas known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

105. As a result of Novartis' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

106. Novartis did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

107. McKee is a private person with direct and independent knowledge of the allegations

of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

108. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF TEXAS:

- (1) Two times the amount of actual damages which the State of Texas has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$10,000 pursuant to V.T.C.A. Hum. Res. Code § 36.025(a)(3) for each false claim which Novartis cause to be presented to the state of Texas;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VI
MASSACHUSETTS CLAIMS ACT

109. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

110. This is a *qui tam* action brought by Steve M. McKee and the State of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 § 5(A) *et seq.*

111. Mass. Gen. Laws Ann. Chap. 12 § 5B provides liability for any person who-

- (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;
- (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
- (9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

112. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

113. Novartis violated Mass. Gen. Laws Ann. Chap. 118E § 41 from at least 1997 to the present by engaging in the fraudulent schemes described herein.

114. Novartis furthermore violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Massachusetts from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Ann.

Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

115. The State of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

116. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Massachusetts in connection with Novartis' fraudulent schemes.

117. Had the State of Massachusetts known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

118. As a result of Novartis' violations of Mass. Gen. Laws Ann. Chap. 12 § 5B, the State of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

119. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5(c)(2) on behalf of himself and the State of Massachusetts.

120. This Court is requested to accept pendant jurisdiction of this related state claim as it is

predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF MASSACHUSETTS:

- (1) Three times the amount of actual damages which the State of Massachusetts has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Massachusetts;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann.Chap. 12, §5F and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VII
TENNESSEE FALSE CLAIMS ACT

121. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

122. This is a *qui tam* action brought by Steve M. McKee and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*

123. § 71-5-182(a)(1) provides liability for any person who-

(A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

(B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

(C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

124. Novartis violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

125. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

126. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Novartis' fraudulent schemes.

127. Had the State of Tennessee known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to

meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

128. As a result of Novartis' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

129. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

130. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF TENNESSEE:

- (1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Tennessee;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;

- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VIII
DELAWARE FALSE CLAIMS AND REPORTING ACT

131. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

132. This is a *qui tam* action brought by Steve M. McKee and the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

133. 6 Del. C. § 1201(a) provides liability for any person who-

- (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
- (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

134. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program.

135. Novartis violated 31 Del. C. § 1005 from at least 1997 to the present by engaging in the fraudulent schemes described herein.

136. Novartis furthermore violated 6 Del. C. § 1201(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and 31 Del. C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

137. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

138. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Novartis' fraudulent schemes.

139. Had the State of Delaware known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

140. As a result of Novartis' violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

141. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of

himself and the State of Delaware.

142. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF DELAWARE:

- (1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Novartis caused to be presented to the State of Delaware;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to 6 Del. C. § 1205, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT IX
NEVADA FALSE CLAIMS ACT

143. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

144. This is a *qui tam* action brought by Steve M. McKee and the State of Nevada to

recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et. seq.*

145. N.R.S. § 357.040(1) provides liability for any person who-

(a) knowingly presents or causes to be presented a false claim for payment or approval;

(b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;

(c) conspires to defraud by obtaining allowance or payment of a false claim;

(h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

146. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

147. Novartis violated N.R.S. § 422.560 from at least 1997 to the present by engaging in the fraudulent schemes described herein.

148. Novartis furthermore violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and N.R.S. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

149. The State of Nevada, by and through the Nevada Medicaid program and other state

health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

150. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Novartis' fraudulent schemes.

151. Had the State of Nevada known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

152. As a result of Novartis' violations of N.R.S. § 357.040(1) the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

153. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

154. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEVADA:

(1) Three times the amount of actual damages which the State of Nevada has

sustained as a result of Novartis' fraudulent schemes;

- (2) A civil penalty of not less than \$2,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Nevada;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT X

LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

155. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

156. This is a *qui tam* action brought by Steve M. McKee and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

157. La. Rev. Stat. Ann. § 438.3 provides-

- (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
- (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
- (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent

claim;

158. In addition, La. Rev. Stat. Ann. § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

159. Novartis violated La. Rev. Stat. Ann. § 438.2(A) from at least 1997 to the present by engaging in the fraudulent schemes described herein.

160. Novartis furthermore violated La. Rev. Stat. Ann. §438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and La. Rev. Stat. Ann. § 438.2(A), and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

161. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

162. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Novartis' fraudulent schemes.

163. Had the State of Louisiana known that Novartis was violating the federal and state

laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

164. As a result of Novartis' violations of La. Rev. Stat. Ann. § 438.3 the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

165. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. §439.1(A) on behalf of himself and the State of Louisiana.

166. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF LOUISIANA:

- (1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Louisiana;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or

- any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
 - (3) An award of reasonable attorneys' fees and costs; and
 - (4) Such further relief as this Court deems equitable and just.

COUNT XI
HAWAII FALSE CLAIMS ACT

167. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

168. This is a *qui tam* action brought by Steve M. McKee and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*

169. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

- (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
- (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
- (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

170. Novartis violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Hawaii from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the

FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

171. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

172. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Novartis' fraudulent schemes.

173. Had the State of Hawaii known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

174. As a result of Novartis' violations of Haw. Rev. Stat. § 661-21(a) the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

175. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

176. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to

the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF HAWAII:

- (1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Novartis' illegal schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Hawaii;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XII

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

177. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

178. This is a *qui tam* action brought by Steve M. McKee and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*

179. Ind. Code § 5-11-5.5-2(b) provides liability for any person who knowingly or

intentionally-

- (1) presents a false claim to the state for payment or approval;
- (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;

* * * * *

- (8) cause or induces another person to perform an act described in subs (1) through (6);

180. Novartis violated Ind. Code § 5-11-5.5-2(b)(8) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

181. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

182. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Novartis' fraudulent schemes.

183. Had the State of Indiana known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on

false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

184. As a result of Novartis' violations of Ind. Code § 5-11-5.5-2(b), the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

185. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Ind. Code Ind. Code § 5-11-5.5-4 on behalf of himself and the State of Indiana.

186. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF INDIANA:

- (1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Indiana;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Ind. Code § 5-11-5.5-6 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and

- (4) Such further relief as this Court deems equitable and just.

COUNT XIII
NEW HAMPSHIRE FALSE CLAIMS ACT

187. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

188. This is a *qui tam* action brought by Steve M. McKee and the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

189. N.H. Rev. Stat. Ann. § 167:61-b(1) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department;

(c) conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

190. Novartis violated N.H. Rev. Stat. Ann. § 167:61-b(1)(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Hampshire from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

191. The State of New Hampshire, by and through the New Hampshire Medicaid program

and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

192. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Hampshire in connection with Novartis' fraudulent schemes.

193. Had the State of Indiana known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

194. As a result of Novartis' violations of N.H. Rev. Stat. Ann. § 167:61-b, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

195. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.H. Rev. Stat. Ann. § 167:61-c(II)(a) on behalf of himself and the State of New Hampshire.

196. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEW HAMPSHIRE:

- (1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of New Hampshire;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to N.H. Rev. Stat. Ann. § 167:61-e and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XIV
MICHIGAN MEDICAID FALSE CLAIM ACT

197. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

198. This is a *qui tam* action brought by Steve M. McKee and the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws 400.601 *et seq.*

199. Mich. Comp. Laws 400.607 provides in relevant part-

- (1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act [citations omitted] upon or against the state, knowing the claim to be false.

* * * * *

200. In addition, Mich. Comp. Laws 400.604 prohibits the solicitation, offer or receipt of any kickback or bribe in connection with the furnishing of goods or services for which payment may be made whole or in part under the Michigan Medicaid program.

201. Novartis violated Mich. Comp. Laws 400.607(1) from at least 1997 to the present by engaging in the fraudulent schemes described herein.

202. Novartis furthermore violated 400.607(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Michigan from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the anti-kickback provisions of the Michigan Medicaid False Claim Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

203. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

204. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Novartis' fraudulent schemes.

205. Had the State of Michigan known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to

meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

206. As a result of Novartis' violations of Mich. Comp. Laws 400.607(1), the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

207. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mich. Comp. Laws 400.610a(1) on behalf of himself and the State of Michigan.

208. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF MICHIGAN

- (1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Michigan;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Mich. Comp. Laws 400.610a(9) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XV
MONTANA FALSE CLAIMS ACT

209. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

210. This is a *qui tam* action brought by Steve M. McKee and the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, Mont. Stat. §17-8-401 *et seq.*

211. Mont. Stat. §17-8-403(1) provides liability for any person who-

- (1) knowingly presents or causes to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity;
- (3) conspires to defraud the governmental entity by getting a false or fraudulent claim allowed or paid by the governmental entity.

212. Novartis violated Mont. Stat. §17-8-403(1)(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Montana from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

213. The State of Montana, by and through the Montana Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

214. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Novartis' fraudulent schemes.

215. Had the State of Montana known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

216. As a result of Novartis' violations of Mont. Stat. §17-8-403(1), the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

217. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mont. Stat. §17-8-406(1) on behalf of himself and the State of Montana.

218. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF MONTANA:

- (1) Three times the amount of actual damages which the State of Montana has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Montana;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Mont. Stat. §17-8-410(1) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XVI
NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

219. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

220. This is a *qui tam* action brought by Steve M. McKee and the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §44-9-1 *et seq.*

221. N.M. Stat. Ann. §44-9-3(A) makes it unlawful to-

- (1) knowingly present, or cause to be presented, to an officer or employee of the State or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;
- (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the

approval of or the payment on a false or fraudulent claim;

(3) conspire to defraud the State by obtaining approval or payment on a false or fraudulent claim.

222. Novartis violated N.M. Stat. Ann. §44-9-3(A)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented by third party payors and others to the State of New Mexico from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

223. The State of New Mexico, by and through the New Mexico Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

224. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Novartis' fraudulent schemes.

225. Had the State of New Mexico known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

226. As a result of Novartis' violations of N.M. Stat. Ann. §44-9-3(A), the State of New

Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

227. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann. §44-9-5(A) on behalf of himself and the State of New Mexico.

228. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEW MEXICO:

- (1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of New Mexico;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to N.M. Stat. Ann. §44-9-7 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XVII
NEW YORK FALSE CLAIMS ACT

229. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

230. This is a *qui tam* action brought by Steve M. McKee and the State of New York to recover treble damages and civil penalties under the New York False Claims Act, New York Fin. Law § 187 *et seq.*

231. New York Fin. Law § 189 provides liability for any person who-

(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;

(c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

232. Novartis violated New York Fin. Law § 189(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

233. The State of New York, by and through the New York Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

234. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Novartis' fraudulent schemes.

235. Had the State of New York known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

236. As a result of Novartis' violations of New York Fin. Law § 189(a), the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

237. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to New York Fin. Law § 190(2) on behalf of himself and the State of New York.

238. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEW YORK:

- (1) Three times the amount of actual damages which the State of New York has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of New York;

- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to New York Fin. Law § 190 (6) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XVIII
VIRGINIA FRAUD AGAINST TAXPAYERS ACT

239. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

240. This is a *qui tam* action brought by Steve M. McKee and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, 842 Virg. Stat. § 8.01-216 *et seq.*

241. 842 Virg. Stat. § 8.01-216.3(A) provides liability for any person who-

- (1) knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
- (3) conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid.

242. Novartis violated 842 Virg. Stat. § 8.01-216.3(A)(1) and knowingly caused hundreds

of thousands of false claims to be made, used and presented to the Commonwealth of Virginia from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

243. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

244. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Novartis' fraudulent schemes.

245. Had the Commonwealth of Virginia known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

246. As a result of Novartis' violations of 842 Virg. Stat. § 8.01-216.3, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

247. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 842 Virg. Stat. § 8.01-216.5 on behalf

of himself and the Commonwealth of Virginia.

248. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the COMMONWEALTH OF VIRGINIA:

- (1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the Commonwealth of Virginia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to 842 Virg. Stat. § 8.01-216.7 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XIX
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

249. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

250. This is a *qui tam* action brought by Steve M. McKee and the District of Columbia to

recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

251. D.C. Code § 2-308.14(a) provides liability for any person who-

- (1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
- (3) conspires to defraud the District by getting a false claim allowed or paid by the District;
- (8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

252. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

- (1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or
- (2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

253. Novartis violated D.C. Code § 4-802(c) from at least 1997 to the present by engaging in the illegal schemes described herein.

254. Novartis furthermore violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal schemes were even eligible for

reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

255. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, and unaware of Novartis' illegal schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

256. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with Novartis' illegal schemes.

257. Had the District of Columbia known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

258. As a result of Novartis' violations of D.C. Code § 2-308.14(a) the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

259. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

260. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the DISTRICT OF COLUMBIA:

- (1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Novartis' illegal schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the District of Columbia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XX
OKLAHOMA MEDICAID FALSE CLAIMS ACT

261. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

262. This is a *qui tam* action brought by Steve M. McKee and the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. §5053 *et seq.*

263. Okla. Stat. §5053.1(B) provides liability for any person who-

- (1) knowingly presents, or causes to be presented, to an officer or

employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

264. Novartis violated 63 Okla. Stat. §5053.1(B)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Oklahoma from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

265. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

266. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Novartis' fraudulent schemes.

267. Had the State of Oklahoma known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care

providers and third party payors in connection with those schemes.

268. As a result of Novartis' violations of 63 Okla. Stat. §5053.1(B)(1), the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

269. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okla. Stat. §5053.2(B)(1) on behalf of himself and the State of Oklahoma.

270. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF OKLAHOMA:

- (1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Oklahoma;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to 63 Okla. Stat. §5053.4 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXI
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

271. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

272. This is a *qui tam* action brought by Steve M. McKee and the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims For Medical Assistance Act, Wis. Stat. §20.931 *et seq.*

273. Wis. Stat. §20.931(2) provides liability for any person who-

- (1) Knowingly presents, or causes to be presented, to any officer, employee, or agent of this state a false claim for medical assistance;
- (2) Knowingly makes, uses or causes to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance;
- (3) Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

274. Novartis violated Wis. Stat. § 20.931(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Wisconsin from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

275. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

276. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Novartis' fraudulent schemes.

277. Had the State of Wisconsin known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

278. As a result of Novartis' violations of Wis. Stat. §20.931(2), the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

279. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. §20.931(5)(a) on behalf of himself and the State of Wisconsin.

280. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF WISCONSIN:

- (1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Wisconsin;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Wis. Stat. §20.931(11) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXII
GEORGIA FALSE MEDICAID CLAIMS ACT

281. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

282. This is a *qui tam* action brought by Steve M. McKee and the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code §49-4-168 *et seq.*

283. Ga. Code §49-4-168.1(a) provides liability for any person who-

- (1) Knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved

by the Georgia Medicaid program;

(3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

284. Novartis violated Ga. Code § 49-4-168.1(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Georgia from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

285. The State of Georgia, by and through the Georgia Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

286. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Novartis' fraudulent schemes.

287. Had the State of Georgia known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

288. As a result of Novartis' violations of Ga. Code § 49-4-168.1(a), the State of Georgia

has been damaged in an amount far in excess of millions of dollars exclusive of interest.

289. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Ga. Code § 49-4-168.2(b) on behalf of himself and the State of Georgia.

290. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF GEORGIA:

- (1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Georgia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Ga. Code § 49-4-168.2(i) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXIII
NEW JERSEY FALSE CLAIMS ACT

291. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

292. This is a *qui tam* action brought by Steve M. McKee and the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J.S.A. §2A:32C-1 *et seq.*

293. N.J.S.A. §2A:32C-3 provides liability for any person who-

- (a) Knowingly presents, or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of state funds, a false or fraudulent claim for payment or approval;
- (b) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
- (c) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

294. Novartis violated N.J.S.A. §2A:32C-3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Jersey from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

295. The State of New Jersey, by and through the New Jersey Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims

submitted by health care providers and third party payors in connection therewith.

296. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Novartis' fraudulent schemes.

297. Had the State of New Jersey known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

298. As a result of Novartis' violations of N.J.S.A. §2A:32C-3, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

299. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J.S.A. §2A:32C-5(b) on behalf of himself and the State of New Jersey.

300. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEW JERSEY:

- (1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Novartis' fraudulent schemes;

- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of New Jersey;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to N.J.S.A. §2A:32C-7 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXIV
RHODE ISLAND FALSE CLAIMS ACT

301. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

302. This is a *qui tam* action brought by Steve M. McKee and the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*

303. R.I. Gen. Laws § 9-1.1-3(a) provides liability for any person who-
- (a) Knowingly presents, or causes to be presented to an employee, officer or agent of the state or a member of the guard a false or fraudulent claim for payment or approval;
 - (b) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
 - (c) Conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

304. Novartis violated R.I. Gen. Laws § 9-1.1-3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Rhode Island from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

305. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

306. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Novartis' fraudulent schemes.

307. Had the State of Rhode Island known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

308. As a result of Novartis' violations of R.I. Gen. Laws § 9-1.1-3(a), the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

309. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws § 9-1.1-4(b) on behalf

of himself and the State of Rhode Island.

310. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF RHODE ISLAND:

- (1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Rhode Island;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-4(d) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXV
CONNECTICUT FALSE CLAIMS ACT

311. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

312. This is a *qui tam* action brought by Steve M. McKee and the State of Connecticut to

recover treble damages and civil penalties under the Connecticut False Claims Act, C.G.S. § 17b-301a *et seq.*

313. C.G.S. § 17b-301b(a) provides liability for any person who-

- (a) Knowingly present, or causes to be presented to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;
- (b) Knowingly make, use or cause to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;
- (c) Conspire to defraud the securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services.

314. Novartis violated C.G.S. § 17b-301b(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Connecticut from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

315. The State of Connecticut, by and through the Connecticut Medicaid Program, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

316. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Connecticut in connection with Novartis'

fraudulent schemes.

317. Had the State of Connecticut known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

318. As a result of Novartis' violations of C.G.S. § 17b-301b(a), the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

319. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to C.G.S. § 17b-301d(a) on behalf of himself and the State of Connecticut.

320. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF CONNECTICUT:

- (1) Three times the amount of actual damages which the State of Connecticut has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Connecticut;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to C.G.S. § 17b-301e and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXVI
NORTH CAROLINA FALSE CLAIMS ACT

321. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

322. This is a *qui tam* action brought by Steve M. McKee and the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*

323. N.C. Gen. Stat. § 1-607(a) provides liability for any person who-

- (a) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
- (b) Knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (c) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section.

324. Novartis violated N.C. Gen. Stat. § 1-607(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of North Carolina from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement

by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

325. The State of North Carolina, by and through the North Carolina Medicaid Program, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

326. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Novartis' fraudulent schemes.

327. Had the State of North Carolina known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

328. As a result of Novartis' violations of N.C. Gen. Stat. § 1-607(a), the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

329. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.C. Gen. Stat. § 1-608(b) on behalf of himself and the State of North Carolina.

330. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the

following damages to the following parties and against Novartis:

To the STATE OF NORTH CAROLINA:

- (1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Novartis caused to be presented to the State of North Carolina;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to N.C. Gen. Stat. § 1-610 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

Dated: August 9, 2010

**UNITED STATES OF AMERICA et al., *ex rel.*
STEVE M. MCKEE**

By: Tracy L. Steckling
One of Relator's Attorneys

Tracy L. Steckling
LAW OFFICE OF TRACY L. STECKLING, LLC
3096 Rose Moon Way
Neenah, WI 54956
(920) 843-2180 (phone)
(920) 486-1234 (fax)
tsteckling@whistlelaw.com

Louis Agre
LAW OFFICE OF LOUIS AGRE
539 Gates Street
Philadelphia, PA 19128-2510
(215) 732-2530 (phone)
(215) 923-1028 (fax)

From: Evan Chesler [CN=Evan Chesler/OU=NYC/O=Cravath]
Sent: Wednesday, September 29, 2010 7:42:55 PM
To: Nina Dillon
Subject: Fw: Novartis

Redacted:
Privilege

----- Forwarded by Evan Chesler/NYC/Cravath on 09/29/2010 03:42 PM -----

From: steve.sokolow@novartis.com
To: ndillon@cravath.com, echesler@cravath.com
Cc: jeff.benjamin@novartis.com
Date: 09/29/2010 12:48 PM
Subject: Fw: Novartis

----- Forwarded by Steve Sokolow/GP/Novartis on 09/29/2010 12:47 PM -----

Ken Schuster/PH/Novartis
09/29/2010 11:59 AM

To: Steve Sokolow/GP/Novartis@PH
cc: Jeff Benjamin/GP/Novartis@PH
Subject Re: Fw: NovartisLink

Redacted:
Privilege

Ken Schuster
Vice President & Treasurer
Novartis Corporation
608 Fifth Avenue 10th Floor
New York, NY 10020
USA
Phone: +1 212 830 2434
Fax: +1 212 830 2492
Cell: +1 862 222 5928
Email : ken.schuster@novartis.com

Steve Sokolow/GP/Novartis
09/29/2010 11:54 AM

To: Jeff Benjamin/GP/Novartis

cc Ken Schuster/PH/Novartis@PH
Subject Fw: Novartis

Ken and Jeff:

Redacted:
Privilege

----- Forwarded by Steve Sokolow/GP/Novartis on 09/29/2010 11:54 AM -----

Evan Chesler <EChesler@cravath.com>
09/29/2010 11:53 AM

To "Steven P. Sokolow , Esq." <steve.sokolow@novartis.com>, "Ms. Nina M. Dillon" <NDillon@cravath.com>
cc
Subject Fwd: Novartis

Begin forwarded message:

From: "Harwell, Randy (USAFLM)" <Randy.Harwell@usdoj.gov>
Date: September 29, 2010 11:18:35 AM EDT
To: echesler@cravath.com
Cc: "Champa, Jessica (CIV)" <Jessica.Champa@usdoj.gov>, "May, Marilyn (USAPAE)" <Marilyn.May@usdoj.gov>
Subject: Novartis

Mr. Chesler, as you know, the settlement agreement for the Novartis cases calls for payment of interest on the settlement amount. We therefore need your best guess as to when the wire will be made so that we can calculate the total amount of the wire. We also need the corporate TIN number and street address for the paperwork associated with this payment. Thank you for your prompt attention to this request.

Randy Harwell
Assistant U.S. Attorney
tel. 813-274-6350
fax 813 274-6198

This e-mail is confidential and may be privileged. Use or disclosure of it by anyone other than a designated addressee is unauthorized. If you are not an intended recipient, please delete this e-mail from the computer on which you received it.

From: Evan Chesler [CN=Evan Chesler/OU=NYC/O=Cravath]
Sent: Friday, September 03, 2010 6:03:47 PM
To: Nina Dillon
Subject: Fw: Novartis
Attachments: novrts fac.PDF

here's one.

----- Forwarded by Evan Chesler/NYC/Cravath on 09/03/2010 02:03 PM -----

From: "Harwell, Randy (USAFLM)" <Randy.Harwell@usdoj.gov>
To: <echesler@cravath.com>
Cc: "Champa, Jessica (CIV)" <Jessica.Champa@usdoj.gov>
Date: 09/03/2010 12:30 PM
Subject: Novartis

Mr. Chesler, I am jointly handling the prosecution of a civil qui tam case on file in the Middle District of Florida in which your client, Novartis Pharmaceuticals Corporation, is the named defendant. My co-counsel is Jessica Champa of the Department of Justice Civil Division, and we are working with the Eastern District of Pennsylvania on resolving a number of issues pertaining to Novartis.

We understand that Novartis has requested a copy of the complaint on file in our district, as part of the settlement process that is underway. The case remains under seal, but we have leave of Court to provide this copy to you. We do so, naturally, with the expectation that you and your client will take whatever steps are necessary to preserve the Court's seal on the case and the complaint generally, until such time as it is lifted by Court order.

As you may appreciate, we are discussing some delicate issues with the relators in this case at the moment, and it would certainly advance overall prospects for a smooth resolution if Novartis would agree to forego contacting counsel for the relators until Tuesday of the coming week, to permit our relator discussions to play out. If you have any questions or concerns about this, or otherwise see a need to contact me, my telephone number is provided below.

Thank you.

Randy Harwell
Assistant U.S. Attorney
tel. 813-274-6350
fax 813 274-6198
<<novrts fac.PDF>> <<Missing Image>>

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

UNITED STATES OF AMERICA
ex rel. JIM AUSTIN and JOHN
MONTGOMERY;
STATE OF FLORIDA ex rel.
JIM AUSTIN and JOHN
MONTGOMERY

Civil Action No.
8:03-CV-1551-T-30-TGW

**FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)**

Plaintiffs

v.

NOVARTIS PHARMACEUTICALS
CORPORATION

Defendant.

FIRST AMENDED FALSE CLAIMS ACT COMPLAINT

Introduction

1. JIM AUSTIN and JOHN MONTGOMERY ("Relators") bring this action on behalf of the UNITED STATES OF AMERICA against NOVARTIS PHARMACEUTICALS CORPORATION (hereinafter referred to as "NOVARTIS"), for treble damages and civil penalties arising from NOVARTIS' conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA"). This action is also brought on behalf of the STATE OF FLORIDA (pursuant to The Florida False Claims Act, Fla. Stat. §§68.081 - 68.092). The violations arise out of requests for payment by Medicaid, TRICARE, and possibly other federally-funded government healthcare programs (hereinafter, sometimes referred to as "Government Programs").

2. The facts and circumstances alleged hereinafter involve: (1) a systematic and very

successful marketing program which caused physicians to prescribe the prescription drug Trileptal for off-label uses for which there were no adequate and controlled studies to support such use as to safety or effectiveness, and for which such uses were not supported by one or more citations included or approved for inclusion in any major compendia as specified by 42 U.S.C. §1396r-8(g)(1)(B)(i) (describing Medicaid coverage); and (2) as a result, false claims were submitted to Medicaid and other federally funded healthcare programs for non-covered uses.

3. As required by the FCA, 31 U.S.C. § 3730(a)(2), the Relators have provided to the Attorney General of the United States and to the United States Attorney for the Middle District of Florida, simultaneous and/or prior to the filing of this First Amended Complaint, a statement of all material evidence and information related to the First Amended Complaint. This disclosure statement is supported by material evidence known to Relators at the time of their filing, establishing the existence of NOVARTIS' legal responsibility for those false claims. Because the statement includes attorney-client communications and work product of Relators' attorneys, and is submitted to the Attorney General and to the United States Attorney in their capacity as potential co-counsel in the litigation, the Relators understand this disclosure to be confidential.

4. As may be required by the Florida False Claims Act, the Relators have provided to the Attorney General/Comptroller of the State of Florida, simultaneous with and/or prior to the filing of this First Amended Complaint, a statement of all material evidence and information ("Disclosure Statement") related to this First Amended Complaint. This "Disclosure Statement" is supported by material evidence known to Relators at the time of the filing of their Complaint, establishing the existence of Defendant's false claims. Because this Disclosure Statement includes attorney-client communications and work product of Relators' attorneys, and is submitted to the STATE OF

FLORIDA in its capacity as potential co-counsel in the litigation, the Relators understand this disclosure to be confidential.

Federal Jurisdiction and Venue

5. The acts proscribed by 31 U.S.C. §3729 *et seq.* and complained of herein occurred in part in the Middle District of Florida, and NOVARTIS does business in the Middle District of Florida. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. 3732 (a), as well as under 28 U.S.C. § 1345. This Court also has jurisdiction over this case for the claims brought on behalf of the STATE OF FLORIDA pursuant to 31 U.S.C. §3732(b), inasmuch as recovery is sought on behalf of said State, which arises from the same transactions and occurrences as the claim brought on behalf of the UNITED STATES.

6. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because NOVARTIS transacts business in this District.

Parties

7. Relator JIM AUSTIN is a resident of North Carolina. He was employed by NOVARTIS (and its predecessor) as a sales representative from 1977 to September, 2002. Relator JOHN MONTGOMERY is a resident of Virginia. He was employed by NOVARTIS (and its predecessor) as a sales representative from 1984 to February, 2004.

8. Relators bring this action based on their direct knowledge and also on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. §3730(e)(4). Notwithstanding same, Relators are an original source of the facts alleged in this Complaint.

9. NOVARTIS is a subsidiary of a world-wide pharmaceutical company engaged in the

development, manufacturing and marketing of pharmaceutical products. It is domiciled in the State of New Jersey, and does business throughout the United States, including in the Middle District of Florida. Its United States parent corporation is Novartis Corporation, located at 608 Fifth Avenue, New York, NY 10020.

10. Novartis AG was formed in December, 1996, when the then top parent company, Ciba-Geigy AG, completed a merger with Sandoz AG, forming a new company called Novartis AG. Effective December 31, 1996, a Charter Amendment was filed changing the U.S. operating company to Novartis Corporation from Ciba Geigy Corporation, as part of a company-wide restructuring in conjunction with the formation of the new parent company. Additionally, Sandoz Corporation, the U.S.-based holding company of Sandoz AG, was merged into Novartis Corporation on December 31, 1996. NOVARTIS, in turn, was formerly known as Sandoz Pharmaceuticals Corporation.

11. At all times relevant hereto, NOVARTIS acted through its agents and employees and the acts of NOVARTIS' agents and employees were within the scope of their agency and employment. The policies and practices alleged in this complaint were, on information and belief, set or ratified at the highest corporate levels of NOVARTIS.

Federal Financial Participation for the Medicaid Program

12. The federal government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. See 42 U.S.C. §§1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. See 42 U.S.C.

§§1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of “the total amount expended ... as medical assistance under the State plan ...” See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as federal financial participation (“FFP”).

13. The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64) is the accounting statement which states, in accordance with 42 C.F.R. §430.30(c), must submit each quarter under title XIX of the Social Security Act (the Act). It shows the state’s actual expenditures for the quarter being reported and previous fiscal years, the recoupment made or refunds received, and income earned on grant funds. These amounts, including the amounts paid for prescription drugs, such as Trileptal, have a direct effect on the amount of FFP paid by the federal government.

New Drug Approval and Off-label Use

14. The Federal Food Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 321 *et seq.*, provides a systematic scheme for the approval of new drugs and new drug formulations intended to be marketed for use in interstate commerce. Under the FDCA, a new drug product cannot be marketed unless the FDA approves the product and determines that it is safe and effective for its intended use. See 21 U.S.C. § 355(a).

15. When the FDA approves a drug, it approves the drug only for the particular use for which it was tested, but after the drug is approved for a particular use, the FDCA does not regulate how the drug may be prescribed. Thus, a drug that has been tested and approved for one use only can also be prescribed by a physician for another use, known as “off-label.”

16. Though physicians may prescribe drugs for off-label usage, the FDA prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. See 21

U.S.C. § 331(d) (prohibiting distribution of drug for non-approved uses); id. § 331(a) (prohibiting distribution of a "misbranded" drug). A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about its unapproved uses.

The Federal False Claims Act

17. The Federal FCA provides, in pertinent part that:

(a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;

* * *

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

Information about the Drug: Trileptal

18. On January 18, 2000, NOVARTIS obtained approval from the FDA to market the prescription drug oxcarbazepine, and NOVARTIS began marketing it under the trade name Trileptal.

19. Trileptal (oxcarbazepine) is an anti-epileptic drug ("AED"), designed to treat symptoms of epilepsy, available as 150 mg, 300mg, and 600 mg film-coated tablets for oral administration (FDA approved on January 14, 2000). Trileptal is also available as a 300 mg/5mL (60mg/mL) oral suspension (FDA approved on May 25, 2001). The FDA package label indication for Trileptal is:

Trileptal (oxcarbazepine) is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy and as adjunctive therapy

in the treatment of partial seizures in children ages 4-16 with Epilepsy.

The FDA approved dosages of Trileptal are: oral suspension (300mg/5mL) and oral tablets (150 mg, 300 mg, and 600 mg).

20. According to the Novartis AG Annual Reports, U.S. sales for Trileptal were approximately \$105 million USD in 2000, \$131 million USD in 2001, and \$255 million USD in 2002. According to NOVARTIS estimates, Trileptal sales will exceed \$300 million in 2003.

21. The NDCs for Trileptal products are as follows:

150 mg Film-coated tablets:

Bottle of 100	NDC 0078-0336-05
Bottle of 1000	NDC 0078-0336-09
Unit Dose (blister pack)	
Box of 100 (strips of 10).....	NDC 0078-0336-06

300 mg Film-coated tablets:

Bottle of 100	NDC 0078-0337-05
Bottle of 1000	NDC 0078-0337-09
Unit Dose (blister pack)	
Box of 100 (strips of 10).....	NDC 0078-0337-06

600 mg Film-coated tablets:

Bottle of 100	NDC 0078-0338-05
Bottle of 1000	NDC 0078-0338-09
Unit Dose (blister pack)	
Box of 100 (strips of 10).....	NDC 0078-0338-06

300 mg/5mL (60mg/mL) Oral Suspension:

Bottle containing 250 mL of oral suspension	NDC 0078-0357-52
--	------------------

Off-Label Marketing: Bipolar Disorder and Neuropathic Pain

22. NOVARTIS successfully marketed Trileptal off-label so that since the first months after it was launched, it has beat out virtually all other competitors in new prescriptions growth. The